PATENT APPLICATION
FILING ACKNOWLEDGMENT

Mailing Date: June 8, 1998 Express Mail No. EM035053295US
File No.: 16355-002520 Attorney: MDB:rjs
Inventor(s): Julian N. Nikolchev, Dai T. Ton, Ashish Khera, Donnel W. Gurskis, and Steven Bacich
Title: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS

Executed Petition to Extend Time in Parent Appn. (In Triplicate)
Unexecuted Declaration
Unexecuted Power of Attorney by Assignee
Unexecuted Verified Statement Claiming Small Entity Status
Unexecuted Assignment Document

No. Pages of Cover Sheet:	One (1)
No. Pages of Specification:	Thirty-two (32)
No. Pages of Claims:	Fifteen (15)
No. Pages of Abstract:	One (1)
No. Sheets of Informal Drawings:	Twelve (12)
NO FEE Cont. Transmittal Sheet:	One (1)

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TOWNSEND and TOWNSEND and CREW LLP

By BRAD FICK

PATENT

Attorney Docket No. 16355-002500

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
JULIAN N. NIKOLCHEV et al.	Examiner: BROWN, M.A.
Application No.: 08/475,252	Art Unit: 3301
Filed: June 7, 1995	
For: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES HAVING MECHANICAL FALLOPIAN TUBE ATTACHMENT	**PETITION TO EXTEND TIME UNDER 37 CFR §1.136(a)**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants petition the Assistant Commissioner of Patents to extend the time for response to the Notice of Appeal filed January 8, 1998, for three (3) months, from March 8, 1998, to June 8, 1998. An appropriate response to the Notice of Appeal in the form of a Continuation Application is enclosed herewith.

Please charge $475.00, pursuant to 37 CFR §1.17, to the Deposit Account No. 20-1430. Please charge any additional fees or credit overpayment to the above Deposit Account. This Petition is submitted in triplicate.

Respectfully submitted,

Mark D. Barrish
Reg. No. 36,443

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
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Atty. Docket No. 16355-002520

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By BRAD FICK

Sir:

Transmitted herewith for filing under 37 CFR §1.53(b) is the continuation patent application of:

Inventor(s)/Applicant Identifier: **JULIAN N. NIKOLCHEV, DAI T. TON, ASHISH KHERA, DONNEL W. GURSKIS, and STEVEN BACICH**

For: **CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS**

[X] **This application claims priority from each of the following Application Nos./filing dates: 60/059,861/September 24, 1997; 08/474,779/June 7, 1995; 08/475,252/June 7, 1995, the disclosures of which are incorporated herein by reference.**

[X] **Please amend this application by adding the following before the first sentence: --This application is a continuation of and claims the benefit of priority from U.S. Provisional Application No. 60/059,861, filed September 24, 1997, which is also a continuation-in-part of U.S. Patent Application No. 08/475,252, and U.S. Patent Application No. 08/474,779, both filed June 7, 1995, the full disclosures of which are incorporated herein by reference.--**

Enclosed are:
[X] **Twelve (12) sheets of informal drawings.**
[X] **Forty-eight (48) pages of specification including description (32), claims (15) and abstract (01).**
[X] **An unsigned assignment of the invention to Conceptus, Inc.** .
[X] **An unsigned Declaration.**
[X] **An unsigned Power of Attorney by Assignee.**
[X] **An unsigned verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27 is enclosed.**
[ ] A certified copy of a _____ application.
[ ] Information Disclosure Statement under 37 CFR 1.97.
[X] **A petition to extend time to respond in the parent application, U.S. Application No. 08/475,252.**
[ ] Notification of change of [ ] power of attorney [ ] correspondence address filed in prior application.
[ ]

Pursuant to 37 CFR §1.53(f), Applicant requests deferral of the filing fee

until submission of the Missing Parts of Application.

DO NOT CHARGE THE FILING FEE AT THIS TIME.

Respectfully submitted,
TOWNSEND and TOWNSEND and CREW LLP

Mark D. Barrish
Reg. No.: 36,443
Attorneys for Applicant

Telephone: (415) 576-0200
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Attorney Docket No. 16355-002520

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS the specification of which _XX_ is attached hereto or ___ was filed on ___ as Application No. ___ and was amended on ___ (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign applications(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119
			Yes _ No _
			Yes _ No _

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date
60/059,861	**September 24, 1997**

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status
08/474,779	June 7, 1995	___ Patented _X_ Pending ___ Abandoned
08/475,252	June 7, 1995	___ Patented _X_ Pending ___ Abandoned

Full Name of Inventor 1	Last Name **NIKOLCHEV**	First Name **JULIAN**	Middle Name or Initial **N.**	
Residence & Citizenship	City **Portola Valley**	State/Foreign Country **California**	Country of Citizenship **United States of America**	
Post Office Address	Post Office Address **251 Durazno Way**	City **Portola Valley**	State/Country **California**	Zip Code **94028**

Full Name of Inventor 2	Last Name **TON**	First Name **DAI**	Middle Name or Initial **T.**	
Residence & Citizenship	City **San Jose**	State/Foreign Country **California**	Country of Citizenship **United States of America**	
Post Office Address	Post Office Address **1693 Flickinger Avenue**	City **San Jose**	State/Country **California**	Zip Code **95131**
Full Name of Inventor 3	Last Name **KHERA**	First Name **ASHISH**	Middle Name or Initial	
Residence & Citizenship	City **San Francisco**	State/Foreign Country **California**	Country of Citizenship **United States of America**	
Post Office Address	Post Office Address **1630 Sanchez Street, #3**	City **San Francisco**	State/Country **California**	Zip Code **94131**
Full Name of Inventor 4	Last Name **GURSKIS**	First Name **DONNELL**	Middle Name or Initial **W.**	
Residence & Citizenship	City **Pleasanton**	State/Foreign Country **California**	Country of Citizenship **United States of America**	
Post Office Address	Post Office Address **3251 Anastacia Court**	City **Pleasanton**	State/Country **California**	Zip Code **94588**
Full Name of Inventor 5	Last Name **BACICH**	First Name **STEVEN**	Middle Name or Initial	
Residence & Citizenship	City **Half Moon Bay**	State/Foreign Country **California**	Country of Citizenship **United States of America**	
Post Office Address	Post Office Address **20 Fairway Place**	City **Half Moon Bay**	State/Country **California**	Zip Code **94019**

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1 **JULIAN N. NIKOLCHEV**	Signature of Inventor 2 **DAI T. TON**
Date	Date
Signature of Inventor 3 **ASHISH KHERA**	Signature of Inventor 4 **DONNELL W. GURSKIS**
Date	Date
Signature of Inventor 5 **STEVEN BACICH**	
Date	

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Attorney Docket No. 16355-002520

POWER OF ATTORNEY BY ASSIGNEE

CONCEPTUS, INC., 1021 Howard Avenue, San Carlos, California 94070, is the Assignee of the invention entitled: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS;

The specification of which XX is attached hereto or ___ was filed on ___ as Application Serial No. ___.

The Assignment accompanying this Power of Attorney has been reviewed by the undersigned. The undersigned certifies that to the best of the undersigned's knowledge and belief, title is in the Assignee. The undersigned (whose title is supplied below) is empowered to act on behalf of the Assignee.

Assignee hereby appoints the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Mark D. Barrish, Reg. No. 36,443
James M. Heslin, Reg. No. 29,541
Gary T. Aka, Reg. No. 29,038
Robert C. Colwell, Reg. No. 27,431
Paul C. Haughey, Reg. No. 31,836
David N. Slone, Reg. No. 28,572
William M. Smith, Reg. No. 30,223
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Darin J. Gibby, Reg. No. 38,464
Hao Y. Tung, Reg. No. P43,209

Send Correspondence to:	Direct Telephone Calls to:
Mark D. Barrish, Esq. TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8th Floor San Francisco, CA 94111-3834	**Mark D. Barrish, Esq.** Reg. No. 36,443 (650) 326-2400

CONCEPTUS, INC.

Date: _____ Signature: _____

Name: _____

Title: _____

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Atty. Docket No. 16355-002520

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN

Applicant or Patentee: JULIAN N. NIKOLCHEV et al.
Application or Patent No.: Serial No. Unassigned
Filed or Issued: Filed June 8, 1998
Title: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS

I hereby declare that I am:

[ ] the owner of the small business concern identified below:
[X] an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Small Business Concern: CONCEPTUS, INC.
Address of Small Business Concern: 1021 Howard Avenue
San Carlos, California 94070

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS by inventor(s) JULIAN N. NIKOLCHEV, DAI T. TON, ASHISH KHERA, DONNELL W. GURSKIS, and STEVEN BACICH described in:

[X] the specification filed herewith.
[ ] Application No. _____, filed _____.
[ ] Patent No. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

Name _____
Address _____
_____
[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

Name _____
Address _____
_____
[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: _____
Title of Person if Other than Owner: _____
Address of Person Signing: _____
_____

Signature _____ Date _____

Attorney Docket No. 16355-002520

ASSIGNMENT OF PATENT APPLICATION

JOINT

WHEREAS,

JULIAN N. NIKOLCHEV of **251 Durazno Way, Portola Valley, California 94028**, **DAI T. TON** of **1693 Flickinger Avenue, San Jose, California 95131**, **ASHISH KHERA** of **1630 Sanchez Street, #3, San Francisco, California 94131**, **DONNELL W. GURSKIS** of **3251 Anastacia Court, Pleasanton, California 94588**, and **STEVEN BACICH** of **20 Fairway Place, Half Moon Bay, California 94019**,

hereinafter referred to as "Assignors," are the inventors of the invention described and set forth in the below identified application for United States Letters Patent:

Title of the Invention: **CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS**

Date(s) of execution of **Declaration**: _____

Filing date: **June 8, 1998** Application No.: **Unassigned**; and

WHEREAS, **CONCEPTUS, INC.**, a **California** corporation, located at **1021 Howard Avenue, San Carlos, California 94070**, hereinafter referred to as "Assignee," is desirous of acquiring an interest in the invention and application and in any Letters Patent and Registrations which may be granted on the same;

For good and valuable consideration, receipt of which is hereby acknowledged by Assignors, Assignors have assigned, and by these presents do assign to Assignee all right, title and interest in and to the invention and application and to all foreign counterparts (including patent, utility model and industrial designs), and in and to any Letters Patent and Registrations which may hereafter be granted on the same in the United States and all countries throughout the world, and to claim the priority from the application as provided by the Paris Convention. The right, title and interest is to be held and enjoyed by Assignee and Assignee's successors and assigns as fully and exclusively as it would have been held and enjoyed by Assignors had this assignment not been made, for the full term of any Letters Patent and Registrations which may be granted thereon, or of any division, renewal, continuation in whole or in part, substitution, conversion, reissue, prolongation or extension thereof.

Assignors further agree that they will, without charge to Assignee, but at Assignee's expense, (a) cooperate with Assignee in the prosecution of U.S. Patent applications and foreign counterparts on the invention and any improvements, (b) execute, verify, acknowledge and deliver all such further papers, including patent applications and instruments of transfer and (c) perform such other acts as Assignee lawfully may request to obtain or maintain Letters Patent and Registrations for the invention and improvements in any and all countries, and to vest title thereto in Assignee, or Assignee's successors and assigns.

Attorney Docket No. 16355-002520

ASSIGNMENT OF PATENT APPLICATION

JOINT

IN TESTIMONY WHEREOF, Assignors have signed their names on the dates indicated.

Date:_____ _____

JULIAN N. NIKOLCHEV

Date:_____ _____

DAI T. TON

Date:_____ _____

ASHISH KHERA

Date:_____ _____

DONNELL W. GURSKIS

Date:_____ _____

STEVEN BACICH

ASSIGN.MRG 9/96
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Attorney Docket No. 16355-002520

PATENT APPLICATION

FOR

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS

Inventors:

JULIAN N. NIKOLCHEV, a citizen of the United States of America, residing at 251 Durazno Way, Portola Valley, California 94028;

DAI T. TON, a citizen of the United States of America, residing at 1693 Flickinger Avenue, San Jose, California 95131;

ASHISH KHERA, a citizen of the United States of America, residing at 1630 Sanchez Street, #3 San Francisco, California 94131;

DONNELL W. GURSKIS, a citizen of the United States of America, residing at 3251 Anastacia Court Pleasanton, California 94588; and

STEVEN BACICH, a citizen of the United States of America, residing at 20 Fairway Place Half Moon Bay, California 94019.

Assignee:

CONCEPTUS, INC.
1021 Howard Avenue
San Carlos, California 94070;
A California corporation.

Status:

Small Entity

TOWNSEND and TOWNSEND and CREW LLP
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PATENT
Attorney Docket No. 16355-002520

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Provisional Application No. 60/059,861, filed September 24, 1997, and is also a continuation-in-part of U.S. Patent Application No. 08/474,779, and Application No. 08/475,252, both filed June 7, 1995, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to contraception, and more particularly to intrafallopian contraceptive devices and nonsurgical methods for their delivery.

Worldwide demand exists for safe, effective methods of both contraception and permanent sterilization. Although a variety of contraception and sterilization methods are available, all of the existing methods have limitations and disadvantages. Thus, the need for additional safe, low cost, reliable methods of contraception and permanent sterilization, both in developed and less developed countries, is widely recognized.

Many presently available contraception methods require significant user involvement, and user non-compliance results in quite high rates of failure. While the theoretical effectiveness of existing contraceptives, including barrier methods and hormonal therapies, is well established, overcoming user noncompliance to improve overall efficacy has proven difficult.

One form of contraception which is less susceptible to user noncompliance is the intrauterine device (IUD). IUDs have been found to have higher rates of reliability, and are effective for a longer period of time, than most other commercially available contraceptives. Unfortunately, IUDs are also associated with serious infectious complications. For this reason, the use of IUDs within the United States has decreased dramatically. Additionally, IUDs are subject to unplanned expulsion, and must be removed due to excessive pain or bleeding in a percentage of cases, further reducing the acceptance of the IUD as a contraceptive method. Interestingly, the efficacy of copper IUDs appears to be higher than that of non-metallic IUDs. The reason for this has not been fully explained.

Commercially available options for permanent sterilization include fallopian tube ligation and vasectomy. These methods are surgical, are difficult to reverse, and are not available to many people in the world. It is common knowledge that fertilization occurs in the fallopian tubes where the sperm and ovum meet. Tubal ligation avoids this by complete occlusion of the fallopian tubes.

It has previously been proposed to reversibly occlude the fallopian tubes, for example, by *in vitro* formation of an elastomeric plug, or otherwise anchoring a device on either side of the narrowest region of fallopian tube, called the "isthmus." Such fallopian tube occlusion methods appear promising; however, an unacceptably high percentage of the non-surgical devices proposed to date have become dislodged during previous studies. Even where non-surgical intrafallopian devices have remained in place, they have been found to be only moderately effective at preventing conception.

For these reasons, it would be desirable to provide effective, reliable intrafallopian devices for contraception and sterilization. It would be particularly desirable to provide highly effective intrafallopian devices which did not require surgery for placement. It would be especially desirable if such devices and methods allowed easy placement

of the device, but were less susceptible to being dislodged than previously proposed non-surgical intrafallopian devices.

2. Description of the Related Art

The experimental use of a stainless steel intrafallopian device is described in *Transcatheter Tubal Sterilization in Rabbits*, Penny L. Ross, RT 29 "Investigative Radiology", pp. 570-573 (1994). The experimental use of an electrolytically pure copper wire as a surgical contraceptive intrafallopian device in rats was described in "Antifertility Effect of an Intrafallopian Tubal Copper Device", D.N. Gupta, 14 *Indian Journal of Experimental Biology*, pp. 316-319 (May 1976).

U.K. Patent Application Pub. No. 2,211,095 describes a uterine screw plug for blocking the fallopian tube. European Patent Application Pub. No. 0,010,812 describes a device for placement in the oviducts having enlargements at either end for anchoring the device. The same device appears to be described in Netherlands Patent No. 7,810,696.

The use of tubal occlusion devices is described in "Hysteroscopic Oviduct Blocking With Formed-in-Place Silicone Rubber Plugs", Robert A. Erb, Ph.D., et al., *The Journal of Reproductive Medicine*, pp. 65-68 (August 1979). A formed-in-place elastomeric tubal occlusion device is described in U.S. Patent No. 3,805,767, issued to Erb. U.S. Patent No. 5,065,751, issued to Wolf, describes a method and apparatus for reversibly occluding a biological tube. U.S. Patent No. 4,612,924, issued to Cimber, describes an intrauterine contraceptive device which seals the mouths of the fallopian tubes.

German Patent No. 28 03 685, issued to Brundin, describes a device for plugging a body duct with a device which swells when in contact with a body fluid.

Alternative contraceptive devices are disclosed in co-pending U.S. Patent Application No. 08/474,779, the full disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

The present invention provides intrafallopian devices and methods for their placement to prevent conception. The intrafallopian devices of the present invention are transcervically delivered and mechanically anchored within the fallopian tube to provide long term contraception, or alternatively permanent sterilization, without the need for surgical procedures or the risks of increased bleeding, pain, and infection associated with intrauterine devices (IUDs).

The intrafallopian devices of the present invention will often comprise a structure having a lumen-traversing region with a helical outer surface. The helical surface is mechanically anchored by a resilient portion of the structure which is biased to form an enlarged secondary shape, preferably forming distal and proximal anchoring loops. The anchoring loops help prevent the helical outer surface from rotating out of position, and also directly deter axial motion within the fallopian tube. In alternative embodiments, anchoring may be provided by a straight coil which is resiliently deflected by the axial curvature of the tortuous fallopian tube, and a radially expandable braid, malecott, or some other tubular structure may help affix the device within the fallopian tube.

The use of copper in the intrafallopian device of the present invention improves its efficacy as a contraceptive method. Devices formed from plastically deformable materials, however, are less readily restrained in the fallopian tube. Apparently, the large variation in the actual shape and dimensions of fallopian tubes does not provide reliable anchoring for a pre-formed deformable intrafallopian device. The intrafallopian device of the present invention therefore often comprises a resilient structure, usually a metallic coil, which includes a copper alloy or plating, ideally comprising an alloy including at least 75% copper. The coil material typically includes beryllium, zinc, stainless steel, platinum, a shape memory alloy, such as Nitinol®, or the like. Preferably, the coil is composed of an alloy of beryllium and copper.

Although the present device will generally result in occlusion, it need not completely occlude the fallopian tube to prevent the meeting of the sperm and ovum. Instead, in some embodiments, the presence of the copper on the resilient structure is sufficient to provide effective contraception. Hence, contraception can be provided by disrupting the normal architecture and/or function of the fallopian tube, despite the presence of an open lumen. This concept is referred to herein as "functional occlusion". As used herein, a device which provides functional occlusion means that the device, when implanted in the fallopian tube, disrupts the normal architecture and/or functioning of the fallopian tube so as to inhibit fertilization and/or conception.

Conveniently, the present invention further comprises non-surgical placement of such intrafallopian devices by transcervical introduction. The resilient structure is restrainable in a straight configuration, e.g., by use of a corewire, greatly facilitating and reducing the risks of introduction. Thus, the cost and dangers associated with existing surgical contraceptive and sterilization procedures are avoided.

In a first aspect, a contraceptive intrafallopian device according to the present invention comprises a proximal anchor, a distal anchor, and a lumen-traversing region extending between the anchors. The lumen traversing region has a helical outer surface and a cross-section which is smaller than the cross-sections of the proximal and distal anchors.

Preferably, the lumen-traversing region comprises a resilient structure, generally having a ribbon wound over the outer surface to form the helical shape. Anchoring is enhanced by a sharp outer edge on the ribbon. As described above, at least one of the proximal anchor, the distal anchor, and the lumen-traversing region preferably comprises copper. The proximal and distal anchors generally comprise a resilient structure biased to form an enlarged secondary shape, thereby allowing the device to be restrained in a straight configuration to facilitate transcervical introduction.

In another aspect, a contraceptive intrafallopian device according to the present invention comprises a primary coil having a proximal loop, a distal loop, and an intermediate straight section between the loops. A helical ribbon is wound over at least a portion of the intermediate section, forming a helical surface to mechanically anchor the device within the fallopian tube. An element is disposed along the coil, and is adapted to incite a tissue reaction in the tubal tissues which inhibits conception.

The ribbon of the present intrafallopian device generally protrudes sufficiently to firmly engage the tubal wall. Preferably, the ribbon has a width in the range between 0.005 and 0.1 inch, a thickness in the range between 0.001 and 0.2 inch, and a pitch in the range between 0.01 and 0.2 inch. The overall device geometry preferably facilitates introduction and retention, but is not large or rigid enough to interfere with internal tissue movements. Usually, the device has a length in the range between 1.5 cm and 7.5 cm when in a relaxed state, while the distal loop and the proximal loop have outer diameters of at least 3.0 mm. Preferably, the primary coil has an outer diameter in the range between 0.2 mm and 5.0 mm.

In another aspect, a system for delivering intrafallopian contraceptive devices according to the present invention comprises a primary coil having a proximal loop, a distal loop, and an intermediate straight section between the loops. Additionally, a lumen extends from a proximal end of the proximal loop to near a distal end of the distal loop. A helical ribbon is wound over at least a portion of the intermediate section, forming a helical surface to mechanically anchor the device within the fallopian tube. A corewire is removably disposed within the lumen of the primary coil. The corewire restrains the primary coil in a straight configuration, facilitating transcervical introduction. Optionally, the corewire is threadably received by the primary coil. Alternatively, a release catheter is slidably disposed over the corewire proximally of the primary coil to restrain

the primary coil while the corewire is withdrawn proximally from the fallopian tube.

The helical ribbon is anchored in the fallopian tube by the distal and proximal loops. The ribbon is set in the tubal wall while the device is restrained in a straight configuration over a corewire by torquing on the corewire. Withdrawing of the corewire then releases the anchors. The distal anchor may be inserted into the ampulla, distal of the isthmus, while the proximal anchor is located in the ostium. These anchors prevent rotation of the device, and also help avoid axial movement. Alternatively, the anchors may be positioned anywhere past the ostium and within the fallopian tube, depending on their length and configuration. Preferably, at least some anchoring is provided along the intramural to isthmic region of the fallopian tube.

In yet another aspect, an intrafallopian contraceptive method according to the principles of the present invention comprises restraining a resilient contraceptive structure in a straight configuration over a corewire, where the resilient structure includes a lumen-traversing region having a helical outer surface. The resilient structure is transcervically introduced into a target region of a fallopian tube, typically in the region of the ostium, and the corewire is withdrawn from the resilient structure. The resilient structure is mechanically anchored within the fallopian tube, a portion of the resilient structure assuming an enlarged secondary shape which is larger in cross-section than the fallopian tube. Optionally, an electric current is applied through the resilient structure to the fallopian tube, thereby effecting permanent sterilization. In fact, such electrosurgical attachment of an intraluminal device to a surrounding lumenal wall may provide effective anchoring even without loops and other anchoring structures. Electrical current may also be used to decouple the intrafallopian device from the delivery system, typically by electrolytically dissolving a solder bond. Current may also actuate an anchor, such as by releasing a resilient radially expandable tubular structure within the fallopian tube.

Tissue Reaction

The present invention also provides improved contraceptive devices which incite a tissue reaction within the fallopian tube to prevent conception. This group of intrafallopian devices will often make use of a highly flexible coil structure to avoid damaging or penetrating through the delicate tubal tissues. The desired tissue reaction may be the result of the material of intrafallopian device, or may be incited by a coating, a surface treatment, a mechanical interaction between the device and the surrounding tubal wall, or the like. The tissue will often help impede conception by occluding the fallopian tube, by interrupting the transport mechanisms of the tubal tissues, and/or by restraining the intrafallopian tubal device within the tube. Specific tissue reactions which may provide these intended results include tissue ingrowth into the contraceptive device and/or the tubal lumen, scar tissue formation, sclerosing of the tubal tissues, and the like.

In one aspect, the invention provides a tissue reaction contraceptive device for use in a fallopian tube. The contraceptive device comprises a coil having a proximal end and a distal end and defining an axis therebetween. The coil is axially flexible and has a cross-section suitable for insertion into the fallopian tube. An element disposed along the coil is adapted to incite a tissue reaction in the tubal tissues adjacent the coil so as to inhibit conception.

In some embodiments, the element may promote ingrowth of the tubal tissues into the contraceptive device. For example, the element may include a braided or woven polyester, a micro-porous material or surface treatment, or the like. Alternatively, a sharp edged helical ribbon or other mechanical interaction element may incite the formation of scar tissue, or a surface coating of the coil may sclerose the tubal tissues, exciting formation of tough fibrous connective tissues which interfere with conceptive transport. In many embodiments, the presence of the contraceptive device in combination with the tissue reaction can provide effective

contraception without having to rely on total occlusion of the fallopian tube.

In another aspect, the present invention provides a tissue ingrowth contraceptive device for use in a fallopian tube. The contraceptive device comprises a tubular retention structure having a proximal end, a distal end and an axis therebetween. The retention structure is axially flexible, and is insertable within the fallopian tube. A material which can incite ingrowth of the tubal tissue is attached to, and exposed radially from, the retention structure.

In the exemplary embodiment, the retention structure comprises a helical coil in which the ingrowth material is disposed. Such helical coils may optionally be radially expansible within the fallopian tube, thereby allowing the device to accommodate a wide variety of tubal physiologies. The ingrowth material may be in the form of braided or woven fibers of polyester, P.T.F.E., or the like.

In another aspect, the present invention provides a tissue ingrowth contraceptive device for use in a fallopian tube. The contraceptive device comprises a resilient elongate body having a proximal end and a distal end and defining an axis therebetween. A retention structure is disposed along the resilient body. The retention structure is adapted to restrain the resilient body within the fallopian tube. A bond affixes the retention structure to the resilient body. At least one of the resilient body, the retention structure, and the bond comprises a micro-porous material which promotes tissue ingrowth therein.

In another aspect, the present invention provides a contraceptive method comprising transcervically inserting a contraceptive device within a fallopian tube. The device is inserting by resiliently deflecting a distal body of the contraceptive device against a tubal wall, so that the distal body guides the contraceptive device axially along the fallopian tube. A tissue reaction is incited with an element of the contraceptive device in the tubal tissues. This tissue reaction affixes the contraceptive device within the fallopian tube.

One Size Fits All

The present invention also provides improved contraceptive devices, systems, and methods adapted for use in the widely varying geometry of the fallopian tube. In recognition of the wide variations in tubal physiology, the contraceptive structures of the present invention are radially expandable within the fallopian tube to engage the tubal wall. Surprisingly, the contraceptive devices of the present invention will often make use of tubular structures such as resilient helical coils. Such tubular devices will often effect contraception by disrupting the architecture and/or transport mechanisms of the tubal tissues, rather than relying entirely on total blockage of the tube. The passages through the tubular contraceptive devices of the present invention may optionally be occluded by promoting tissue ingrowth within the device, for example, by including woven or braided polyester fibers within a helical coil. Regardless, such tubular retention structures are capable of radially expanding against tubal walls throughout a wide range of tubal sizes to safely anchor the contraceptive device, without having to resort to protruding barbs or the like.

In one aspect, the present invention provides a contraceptive device for use in fallopian tube having a tubal wall. The contraceptive device comprises a tubular retention structure having a proximal end, a distal end, and an axis therebetween. The retention structure is radially expandable *in situ* from a narrow configuration (in which the retention structure has a first diameter which is suitable for axial insertion into the fallopian tube) so as to define a second, enlarged diameter. The expanded retention structure is adapted to engage the surrounding tubal wall and retain the contraceptive device within the fallopian tube.

In another aspect, the present invention provides a contraceptive device for use in a fallopian tube having a tubal wall. The contraceptive device comprises a conception inhibiting body which defines an axis. A helical coil is disposed about the body. A portion of the helical coil is

movable relative to the body so that the helical coil can expand resiliently throughout a range of tubal cross-sectional sizes. Hence, the coil can radially engage the surrounding tubal wall and safely affix the contraceptive device within the fallopian tube.

Straight Coil

The present invention also provides intrafallopian contraceptive devices having elongate coils which are substantially straight. Surprisingly, when such straight coils are positioned axially within the tortuous fallopian tubes, the bends imposed on the coil by the fallopian tube can result in resilient anchoring of the coil. Such straight coils are also highly advantageous when advancing the contraceptive device into (and within) the fallopian tube. Straight resilient coils can act as an integral guidewire during transcervical deployment of the device within the fallopian tube, thereby avoiding the delay associated with the sequential use of guidewires, tubal axis catheters, and the like.

The present invention provides an intrafallopian contraceptive device for use in a fallopian tube. The contraceptive device comprises an elongate coil having a proximal end, a distal end, and an axis therebetween. The axis is substantially straight when the coil is at rest, and the coil is axially resilient to facilitate insertion of the body axially into the tube. The device is adapted to be retained within the fallopian tube so as to inhibit conception.

In another aspect, the present invention provides an intrafallopian contraceptive device for use in a fallopian tube. The tube has a tubal wall with a tubal cross-section and an axial curvature. The contraceptive device comprises an elongate body having a proximal end and a distal end and defining an axis therebetween. The body has a cross-section suitable for axial insertion within the tubal cross-section. At least a portion of the body is straighter than the axial

curvature of the fallopian tube. The body is sufficiently flexible to deflect against the tubal wall without injuring the tubal wall. The body is also sufficiently resilient to impose an anchoring force against the tubal wall when the straight portion flexes along the axial curvature of the fallopian tube.

In another aspect, the present invention provides a contraceptive device for use in a fallopian tube having an axis. The contraceptive device comprises a structure having a proximal end, a distal end, and an axis therebetween. The structure is adapted to provide effective tubal occlusion when disposed substantially coaxially within the fallopian tube. An elongate member is affixed to the occlusion structure. The member extends distally of the occlusion structure and is sufficiently flexible and axially resilient to help guide distal advancement of the occlusion structure within the fallopian tube.

In a contraceptive method provided by the present invention, an elongate resilient body is transcervically inserted into an axially curving fallopian tube so that the fallopian tube imposes an axial bend on the body. The bent body imposes an anchoring force which helps anchor the bent body within the fallopian tube. The body is anchored within the fallopian tube so that the affixed resilient body inhibits conception.

In another aspect, the present invention provides a contraceptive method comprising transcervically inserting an intrafallopian contraceptive device along the fallopian tube by guiding the contraceptive device with a distal guidewire-like structure of the contraceptive device. The device, including at least a portion of the guidewire-like structure, is retained within the fallopian tube so that the device inhibits conception.

In another aspect, the present invention provides a contraceptive kit. The kit comprises an intrafallopian contraceptive device and instructions for its use. The instructions describe and/or set forth the method steps of transcervically introducing the contraceptive device into a

fallopian tube and affixing the contraceptive device within the tube. Optionally, a variety of delivery structures may also be provided in the kit, including guidewires, corewires, delivery catheters, and the like.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of a contraceptive intrafallopian device according to the present invention.

Fig. 2 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 1.

Fig. 3 illustrates a secondary coil which has been imposed on a primary coil as used in the contraceptive intrafallopian device of Fig. 1.

Fig. 4 illustrates a corewire for use with the contraceptive intrafallopian device of Fig. 1.

Fig. 5 is a cross-sectional view of a contraceptive delivery system having the contraceptive intrafallopian device of Fig. 1.

Fig. 6 illustrates an alternative embodiment of the present contraceptive intrafallopian device.

Fig. 7 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 6.

Fig. 8 schematically illustrates a contraceptive delivery system including the contraceptive intrafallopian device of Fig. 6.

Figs. 9 and 10 illustrates a method of delivery of a contraceptive intrafallopian device according to the present invention.

Figs. 11A-D illustrate intrafallopian contraceptive devices having straight primary coils, together with associated delivery devices and systems.

Figs. 12A-E illustrate a variety of intrafallopian contraceptive devices which are adapted to promote a tissue reaction that enhances the contraceptive efficacy of the device.

Fig. 13 illustrates a method for introducing a dense braid of fiber material into a helical coil of a contraceptive device.

Figs. 14-14E illustrate helical coils which adapt to varying tubal sizes to enhance retention of the contraceptive device within the fallopian tube.

Fig. 15A-D illustrate cross-sectional views through the fallopian tube before, during, and after delivery of a contraceptive device having a radially expandable helical coil, and also illustrates the enhanced efficacy provided by tissue reactions such as tissue ingrowth into and around the helical coil.

Fig. 15E illustrates the self-guiding capabilities of a contraceptive device having a straight primary coil.

Fig. 16 illustrates a contraceptive delivery system having a detachable distal corewire.

Fig. 17 schematically illustrates a kit including a contraceptive delivery system and instructions for its use.

Figs. 18A-C schematically illustrate alternative tubular radially expandable retention structures which can mechanically anchor a contraceptive device in the fallopian tube.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENT

The present invention encompasses a contraceptive intrafallopian device which can alternatively be used as both a permanent and a reversible means of contraception. The present contraceptive methods and devices minimize the danger of non-use which has limited the efficacy of prior art contraceptive techniques. Moreover, the location of the present devices within the fallopian tubes provides a reduced risk of the infectious complications, increased bleeding, and pelvic pain associated with intrauterine devices (IUDs). The location and the novel shape of the present intrafallopian device provides significant advantages over IUDs, which have been found to be susceptible to unplanned expulsion and removal due to excessive pain and bleeding. The present

invention takes advantage of the increase in effectiveness associated with copper IUDs, providing a resilient structure including copper which may be transcervically positioned without the need for surgery.

Although the present contraceptive method is included within a group of contraceptive techniques generally referred to as fallopian tube occlusion methods, the present invention does not necessarily rely solely on blocking the fallopian tube to prevent fertilization. Instead, contraception is apparently provided by disrupting of ovum transport, the process of fertilization, and/or cleavage of the ovum. While the effect that copper has on these processes is not fully understood, it does appear that copper intrafallopian devices offer potentially significant increases in effectiveness over intrafallopian devices formed of other materials. Contraception may alternatively be provided or enhanced by a spermicidal agent attached to the device. Optionally, the present invention further encompasses devices which promote the growth of tissue within the tube to induce tubal occlusion, further inhibiting conception. In some embodiments, polyester fibers such as Dacron®, Rayon®, or the like, are bonded to the surface of the coil using a polymeric adhesive. The polyester fibers promote increased tissue growth around the coil, thus further reducing the possibility of expulsion of the device from the fallopian tube.

Conveniently, the present resilient structures are adapted to be releasably affixed over a corewire, the corewire restraining the resilient structure in a straight configuration. As the resilient structure has an outer diameter when in the straight configuration which is less than the inner diameter of the fallopian tube, the catheter containing the present intrafallopian device is easily transcervically introduced.

The present invention may be anchored within the isthmus of the fallopian tube, overcoming the unintended expulsion of the device and the resulting failure of the contraceptive method. Such intrafallopian device expulsion has been the single greatest factor limiting the efficacy of

easily positioned intrafallopian contraceptive techniques. The present intrafallopian devices are generally elongate resilient structures pre-formed into secondary shapes. These secondary shapes will preferably form anchors proximally and distally of the narrowest portion of the fallopian tube, called the isthmus. The secondary shape preferably has a larger outer diameter than the inner diameter of the isthmus. Anchoring may also be possible with a structure spanning other portions of the tubal lumen, often between the ostial opening and the isthmus.

The present device is generally readily removed by snaring the resilient structure near the proximal end and pulling proximally on the resilient structure, thereby straightening the resilient structure and allowing it to be withdrawn without injuring the fallopian tube. Alternatively, an electrical current is applied to the device after it is positioned within the fallopian tube, providing permanent sterilization. Electrical current might also effect detachment of the device from the delivery system using a system similar to that described in U.S. Patent No. 5,624,449, the full disclosure of which is incorporated herein by reference. *In situ* actuation of an anchor might be effected by releasing a resilient structure to expand *in situ* with a similar mechanism, or by a current induced phase change of a shape memory alloy (for example, causing a straight Nitinol® ribbon to curl within the fallopian tube with a current).

Referring now to Fig. 1, a first embodiment of the present contraceptive intrafallopian device 10 is formed from a resilient primary coil 12. Primary coil 12 has a proximal end 14 and a distal end 16, the latter having an atraumatic endcap 18. Primary coil 12 further includes three portions: a proximal anchor portion 20, a distal anchor portion 22, and a lumen-traversing region 24. Proximal and distal anchors 20,22 are biased to form anchoring loops 26, as described hereinbelow.

Lumen-traversing region 24 comprises a substantially straight portion of primary coil 12. A ribbon 28 is wound over the outer surface of primary coil 12 to provide a helical

shape. Ribbon 28 includes sharp outer edges 29, which firmly anchor lumen-traversing region 24 in the fallopian tube wall when torque is applied to intrafallopian device 10. The ribbon is preferably formed of a high strength biocompatible metal, ideally being stainless steel. The ribbon is attached to primary coil 12 at a proximal joint 30 and a distal joint 32, which may be formed of solder, heat-shrink tubing, or the like.

Referring now to Fig. 2, primary coil 12 is most easily formed in a straight configuration as a cylindrical coil or spring, preferably having an outer diameter in the range from 0.005 inch to 0.05 inch, and having a length in the range from 20 mm to 150 mm. Ideally, primary coil 12 has an outer diameter in the range from 0.01 inch to 0.05 inch and a length in the range from 30 mm to 125 mm.

Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. Such a beryllium copper wire will typically have a diameter from 0.002 inch to 0.01 inch. To provide the increased efficacy of a copper intrafallopian device, primary coil 12 preferably comprises an alloy including 75% copper. Alternatively, primary coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like. If such materials are used, primary coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

Primary coil 12 includes a body winding 42 and a thread winding 44. Body winding 42 is formed with the minimum possible pitch to increase the stiffness of primary coil 12. Thread winding 44 will typically comprise from 0.1 cm to 2.0 cm adjacent to proximal end 14, and will have a pitch roughly twice that of body winding 42.

Referring now to Fig. 3, the proximal and distal anchors are formed by imposing a bent secondary shape on selected portions of primary coil 12. The secondary shape preferably comprises loops 26 formed by bending primary coil

12, and heat treating the primary coil while it is bent. A wide variety of secondary shapes may be used, including sinusoidal curves, alternating loops, or loops separated by straight sections so as to form a "flower coil," as more fully described in co-pending U.S. Patent Application No. 08/474,779, the full disclosure of which is herein incorporated by reference. In most cases, the bent secondary shape will have an outer cross-section 46 which is larger than the fallopian tube to provide effective anchoring.

Referring now to Fig. 4, a corewire 50 for use with intrafallopian device 10 (Fig. 1) comprises a resilient wire 52 which tapers towards a distal end 54. Wire 52 is sufficiently stiff to restrain intrafallopian device 10 in a straight configuration, typically comprising stainless steel, platinum, or the like. A short section of coil forms corewire threads 56 attached at threadjoint 58. Threads 56 match the windings and pitch of threadwindings 44 of primary coil 12.

Referring now to Fig. 5, an intrafallopian contraceptive system 60 comprises corewire 50 inserted within a lumen 62 through intrafallopian device 10. Intrafallopian device 10 is releasably attached by engaging thread windings 44 with threads 56. Thus, intrafallopian device 10 is disengaged by torquing a proximal end of corewire 50 once intrafallopian device 10 is in position.

Referring now to Fig. 6, an alternative embodiment of the present intrafallopian device is again formed from a resilient primary coil 112 having a proximal end 114 and a distal end 116. The former includes a friction fitting 115. Primary coil 112 again includes three portions: a proximal anchor portion 120, a distal anchor portion 122, and a lumen-traversing region 124. Proximal and distal anchors 120, 122 are here biased to form opposed anchoring loops 26, thereby increasing the relaxed overall cross-section of the proximal and distal anchors. A ribbon 128 is wound over the outer surface of primary coil 112 to provide a helical shape, as described above.

Referring now to Fig. 7, primary coil 112 comprises a uniform body winding 142. The secondary shape is imposed on

the straight cylindrical coil as opposed loops 126, or alternatively as multiple loops of a flower coil.

Referring now to Fig. 8, an intrafallopian contraceptive system using alternative intrafallopian device 100 includes a corewire 152 which tapers towards a distal end 154. Friction fitting 115 fittingly engages corewire 152, which restrains primary coil 112 in a straight configuration. A release catheter 164 is slidably disposed over corewire 152 proximally of alternative intrafallopian device 100, allowing the device to be released by withdrawing corewire 152 relative to the release catheter.

Use of the present contraceptive intrafallopian device will be described with reference to Figs. 9 and 10. A uterine introducer canula 70 is inserted transcervically through a uterus 72 to the region of an ostium 74. Alternatively, a hysteroscope may be used in place of canula 70, or an echogenic and/or radiopaque device might be placed under sonographic or radiopaque guidance.

Intrafallopian contraceptive system 60 is advanced distally of introducer cannula 70 and maneuvered through the fallopian tube, preferably until intrafallopian device 10 extends distally of the isthmus. Optionally, intrafallopian contraceptive system 60 is self-guided, with corewire 52 bent near distal end 54 to assist intraluminal maneuvering. Alternatively, a guide wire and catheter are advanced into the fallopian tube first, and the guide wire is replaced with intrafallopian contraceptive system 60. In either case, the intrafallopian device will generally be axially positioned with lumen-traversing region 24 within a target region 84 adjacent to isthmus 80. Preferably, at least one loop of distal anchor 22 is distal of target region 84, and at least one loop of proximal anchor 20 is proximal of target region 84 to form the distal and proximal anchor bends.

Once intrafallopian device 10 is properly positioned, corewire 50 is torqued to set ribbon 28 in the tubal wall. The corewire may then be unthreaded from intrafallopian device 10 by rotating the corewire in the opposite direction, disengaging threads 56 from thread

windings 44. The corewire is then free to slide proximally, releasing the primary coil. As the distal end of the primary coil is released, a distal anchor bend 90 is formed. Similarly, a proximal loop forms a proximal anchor bend 92. The anchor bends help to axially restrain the device within the fallopian tube, and also prevent rotation around the helical shape of lumen-traversing region 24. As seen in Fig. 10, the loops need not assume their relaxed form to provide effective distal or proximal anchors.

The present invention further encompasses permanent sterilization by passing a current through the corewire to the intrafallopian device prior to withdrawing the corewire. Fallopian tube tissue in contact with the intrafallopian device is desiccated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the corewire/primary coil interface must be conductive to allow the present non-surgical method of permanent sterilization.

The intrafallopian contraceptive methods and devices of the present invention can provide highly effective contraception even when the contraceptive device does not totally occlude the lumen of the fallopian tube. To minimize distention of the delicate tubal tissue, the present invention will often leave some open lumen within the fallopian tube, at least when initially deployed. In fact, these contraceptive devices will often comprise perforate tubular structures having lumens. Nonetheless, contraception can be provided by disrupting the normal architecture and/or function of the fallopian tube, despite the presence of an open lumen. This concept is referred to herein as "functional occlusion". As used herein, a device which provides functional occlusion means that the device, when implanted in the fallopian tube, disrupts the normal architecture and/or functioning of the fallopian tube so as to inhibit fertilization and/or conception.

The size of an occlusive device required to provide functional occlusion may depend on the material of the device, the position the device is to be deployed within the fallopian tube, the interaction between the device and the surrounding tubal wall, and the like. For example, intrafallopian contraceptive structures which include fibers of polyester may incite ingrowth of the tubal tissues into the device. As a result of this tissue/device interaction, a relatively small device which promotes ingrowth may be capable of providing effective occlusion. In fact, such a device may be capable of providing total occlusion by inciting sufficient ingrowth so that the hyperplastic tubal walls, in combination with the device, block all passage through the tubal lumen. Hence, relatively small, easily inserted structures may effectively inhibit conception without the danger of distending the tubal wall.

One easily inserted intrafallopian contraceptive structure which may be capable of providing effective tubal occlusion is illustrated in Fig. 11A. A straight contraceptive device 200 includes a straight primary coil 202 around which is disposed a secondary helical coil 204 as described above. Secondary coil 204 is affixed to primary coil 202 at a pair of bonds 206. As illustrated above in Fig. 6, the secondary helical coil may have an inner surface which is larger than the outer surface of primary coil 202, which may facilitate embedding the corners of the secondary coil in the surrounding tubular wall. However, unlike the intrafallopian devices described hereinabove, straight device 200 remains substantially straight between a proximal end 208 and a distal end 210 when the primary coil is at rest.

Primary coil 202 will typically be formed from wire having a diameter of between about 0.002 and 0.009 inches, by winding the wire to form a coil having a diameter between about 0.010 and 0.040 inches. Primary coil 202 will often have a length of between 2.9 and 3.5 cm. The ribbon used to form secondary helical coil 204 will generally have a width between about 0.005 and 0.020 inches, and a thickness of between about 0.0005 and 0.005 inches.

In the exemplary embodiment, straight device 200 includes a primary coil 202 having a total length of between about 3.0 and 3.35 cm. The exemplary primary coil 202 is wound from platinum wire, the platinum wire having a thickness of 0.005 inches, which is wound to provide a primary coil having an outer diameter of about 0.018 inches and a length of about 3.0 cm. Secondary coil 204 is formed from a platinum ribbon having a width of 0.012 inches and a thickness of 0.002 inches. Bonds 206 comprise gold solder and secondary coil 204 has a length of about 0.5 to 1.0 cm and an outer diameter of between about 0.035 to 0.040 inches when affixed to the primary coil 202. Solder is also used to form an atraumatic tip at distal end 210.

Referring now to Figs. 11B and 11C, a self-guiding contraceptive delivery system 212 includes straight contraceptive device 200 and a flexible tip corewire 214. As described above, threads 216 on flexible tip corewire 214 mate with the proximal end 208 of straight contraceptive device 200, the threads ideally comprising a stainless steel coil having approximately the same dimensions as primary coil 202 and affixed to the corewire with yet another gold solder joint 206.

Advantageously, distal end 218 of corewire 214 need not have sufficient stiffness and strength to restrain a coil biased to form a bent secondary shape. As a result, the thickness of corewire 214 may be optimized to enhance the trackability and pushability of self-guided contraceptive system 212, thereby enhancing the ability of the contraceptive system to act as its own guidewire.

Delivery of the contraceptive device is facilitated by using a corewire having a relatively long, stiff proximal section and a relatively short, flexible section, the flexible section typically being tapered as illustrated. The thickness and material properties of these sections are selected to provide enough column strength to allow corewire 214 to advance straight device 200 within the fallopian tube, but enough flexibility at the distal end of the delivery system for distal end 210 to navigate the tortuous fallopian tube. A

relatively thick proximal section also improves the torque transmission capabilities of the wire, particularly for torquing and embedding the outer coil against the tubal wall.

Proximal section 220 of corewire 214 will preferably be flexible enough for delivery through a flexible catheter and/or through the working channel of an endoscope. The corewire will generally comprise a material which resists kinking and resiliently returns to its original shape, ideally comprising a shape memory alloy such as Nitinol® or a treated stainless steel. Such resilience may be tailored to enhance the ability of the delivery system to access the tubal ostium and advance the contraceptive device into the fallopian tube. In some embodiments, corewire 214 will be capable of transmitting heat, electrical current, and/or some other energy which induces scarring, electrocautery, or the like, so as to attach the contraceptive device within the fallopian tube. Alternatively, the transmitted energy may decouple the device from the corewire, for example, by melting a coupler.

In a particularly advantageous aspect, threads 216 of delivery system 200 may be adapted to enhance visualization of the detachment process. For example, a first portion of the threads 222 may be a first color (such as green) while a second portion of the threads 224 may be a second color which contrasts sharply with the first color (such as red). As they are near the proximal end of the device, threads 216 will often be more visible than the remainder of the contraceptive device. The threads may even protrude through the tubal os into the uterus for viewing through the hysteroscope. By visually monitoring highly contrasting colors of the thread portions through the hysteroscope, the attending physician will be provided with direct feedback on the decoupling process. The thread portions may be colored by coating, anodizing, oxidation, polishing, the use of differing materials, or the like. A stripe or other mark may also be provided on the delivery wire to help monitor rotation. Alternative embodiments may use threads having high contrast under imaging.

Still further capabilities may be incorporated into the delivery system. For example, a "smart" delivery device may be able to sense its position within the fallopian tube magnetically, electrically, optically, ultrasonically, or the like. Similarly, the deployed device may incorporate structures which allow the physician to remotely verify the position and presence of the device without having to access the fallopian tube (e.g., using a magnetic sensor, impedance, and/or radio activity).

In the exemplary embodiment, corewire 214 comprises a shape memory alloy such as Nitinol®. Proximal portion 220 of corewire 214 has a thickness of between about 0.018 and 0.040 inches, ideally being about 0.035 cm, and the corewire tapers over a length of about 5.0 cm to a minimum thickness of between about 0.002 and 0.008 inches, typically about 0.003 inches at distal end 218.

One method for attaching polyester fibers 226 to straight contraceptive device 200 is illustrated in Fig. 11D. As described above, such polyester fibers promote tissue ingrowth, which can help affix the device within the fallopian tube. Additionally, such tissue ingrowth may also help to further occlude the lumen of the fallopian tube. Fibers 226 are shown tied in loops around the secondary coil, ideally using between about 5 and 7 loops and fiber.

A wide variety of alternative mechanisms may be employed to incite a tissue reaction which enhances the functional occlusion of the intrafallopian contraceptive device. For example, materials such as collagen, hydroxyapatite, solid or fibrous PTFE, or the like may be used. Biodegradable coatings may cause tissue ingrowth or scarring, and then degrade to leave a fully or partially occluded lumen. In some embodiments, the engagement between outer coil 204 and the tubal wall injures the epithelial tissues, and the healing process results in the formation of scar tissues which interfere with the functioning of the fallopian tube.

A variety of alternative ingrowth promoting intrafallopian contraceptive devices are illustrated in Figs.

12A-E. Generally, each of these devices includes some element which promotes ingrowth of tubal tissues therein. A porous secondary coil 230 may be formed of a porous metal, ideally comprising a micro-porous shape memory alloy such as Nitinol®. In some embodiments, ingrowth bonds 232 may be formed of, or coated with, a material such as bioglass, ceramics, or the like so as to promote tissue ingrowth, so that the entire device may promote ingrowth. Surface treatments may also encourage ingrowth. For example, blasting a surface with small particulates can create a somewhat divoted and porous texture. Such porous textures at the surface, with micron-sized pores, may produce the desired tissue reaction. Alternative embodiments may include an open cell ingrowth promoting structure, such as the open cell foams used to attach some breast implants.

In some embodiments, discrete bodies 234 may be formed as rings or annular beads using any of the above listed tissue ingrowth materials, coatings, or treatments. Wound, wrapped, or braided fiber material 236 may also be disposed between the primary and secondary coils, the fiber material typically comprising a polyester such as Dacron®, Vicril®, or the like. Dense fiber materials within the device may enhance the reaction and/or ingrowth of the surrounding tubal tissues, and also decreases the amount of open space within the device, thereby minimizing any prosthetic lumen. Fiber material 236 may also be in the form of a thick felt, or may simply be spun with several layers of windings.

Still further alternative ingrowth promoting elements are possible, such as tubular fabric 238 of felt, braided or woven material, or the like. Tubular fabric 238 provides an open conduit at the proximal end of the device to avoid impeding with the removal of the corewire, and the outer diameter of the tubular fabric will preferably be less than the outer diameter of the secondary coil. In some embodiments, simply providing an internal fabric 240 in the form of a textile mesh or felt inside the primary coil may be sufficient to incite ingrowth of the tubal tissues into the

coil, affixing the coil in place and providing functional occlusion of the fallopian tube.

Referring now to Fig. 13, a particularly advantageous method for producing a contraceptive device having a dense fiber braid 250 is illustrated. Dense fiber braid 250 is initially formed by wrapping several layers of fiber around a mandrel. After about fifteen layers of fiber have been wrapped over the mandrel, the wound fiber is slid off the mandrel, and the windings are processed to form the braid. The braid is affixed to contraceptive device 200 adjacent one of the bonds, and the fiber braid is then wound between the windings of secondary coil 204. As a result, at least a portion of fiber tube 250 is disposed in the annular space between the primary coil and secondary coil 204. Often times, some portion of the fiber will also extend radially beyond secondary coil 204, as illustrated.

The use of dense fiber braid 250 provides a much greater amount of fiber and a more radially compact, easily deployable assembly than a structure which includes loops tied radially around the secondary coil. Such densely packed fiber thereby makes use of an otherwise open space, and the enhanced amount of fiber should provoke a more robust tissue reaction. Specifically, dense fiber braid 250 will have a smaller pore size, which is generally advantageous for tissue ingrowth. This combination of an enhanced tissue reaction, with a less axially open design, would appear to provide significant advantages for functional occlusion of the fallopian tube.

A still further alternative intrafallopian contraceptive device 200' is illustrated in Fig. 14. Alternative device 200' includes several of the same primary structures described hereinabove regarding straight contraceptive device 200, but makes use of a fiber tube 252 to provide the advantages of high fiber density and a small radial package. In this embodiment, the fiber is again wrapped around a mandrel several times (ideally about 15 times) and then removed as a fiber tube. Tube 252 is slid off the mandrel and onto the primary coil. The tube may be positioned before or after secondary coil 204 is attached at

bond 206, and will generally occupy the annular space between the primary and secondary coils. The ends of tube 252 can be tied to keep the tube in position during delivery.

Alternative contraceptive device 200' also differs from the previous structures in that secondary coil 204 has a free end 254 which is not affixed to primary coil 202. As free end 254 can move relative to primary coil 200, secondary coil 204 can expand radially well beyond bond 206, and can also be radially compressed to provide a very small outer diameter during delivery of the device. Hence, the diameter of secondary coil 204 in alternative device 200' provides a highly radially variable tubular structure which can easily adapt to a wide variety of tubal lumen cross-sectional sizes to retain the contraceptive device within the fallopian tube.

A highly radially expandable tubular retention structure has several significant advantages. First, the structure can be inserted in a narrow profile configuration and radially expanded within the fallopian tube to provide a secure anchor with minimal danger of protruding through the delicate tubal wall. Additionally, the stiffness of the helical secondary coil can be tailored to provide the appropriate engagement force and/or damage to the wall tissue so as to provoke the desired tissue reaction, whether it be scar tissue formation, ingrowth, or the like. Torquing of a free ended helical coil may also be used to adjust the outer diameter during delivery.

The enhanced variability in outer diameter provided by an outer coil 204 having a free end 254 can be understood with reference to Figs. 14A-C. Generally, outer coil 204 will here have an outer diameter of over about 0.080 mm in its relaxed state, the outer diameter of the secondary coil preferably being biased to form a helix with an outer diameter of about 1.0 mm when at rest, and will ideally be compressible to an outer diameter of 0.1 mm for insertion. Outer coil 204 of alternative device 200' may be easily radially compressed by drawing free end 254 proximally away from bond 206, by wrapping the free end around primary coil 202, or by some combination of both.

As illustrated in Figs. 14B and C, the device may be restrained in a small diameter configuration by a delivery catheter 256, by articulatable jaws 258, or the like. Regardless, secondary coil 204 will generally be restrained until the device is positioned within the fallopian tube, and will then be released *in situ* by axially withdrawing catheter 256, articulating jaws 258, or the like. Still further alternative *in situ* release mechanisms are possible, such as dissolving or dissipating a crystal or electrolytic coating which radially restrains the secondary coil, a phase change in a shape memory alloy, or the like, as described above. It should be noted that the free ended secondary coil is illustrated in Figs. 14A-C without the optional dense fiber tube of Fig. 14A for clarity. Nonetheless, the enhanced radial variability provided by a free ended helical coil (or by other perforate tubular structures) may be either used alone or combined with other tissue reaction structures described hereinabove to provide functional occlusion and contraception.

Alternative helical retention structures are illustrated in Figs. 14D and 14E. A tapered coil 203 may be advanced distally, either axially or by rotationally threading the device, to embed the structure into a tapering portion of the tubal wall. The device can accommodate a variety of tubal sizes, as it need only be advanced until proper engagement has been achieved. Variable stiffness along the outer coil may be provided by a coil formed with a tapering ribbon 207, or the like.

The use of a tubular, radially expandable intrafallopian device, and also the significance of tissue reaction in providing functional occlusion, can be further understood with reference to Figs. 15A-D. A lumen L of a fallopian tube F is largely a potential space, much like a deflated balloon. Tubal wall W can expand around structures which are inserted into lumen L, such as around catheter 256 which radially restrains a free ended secondary coil 204. Hence, the size of the irregular lumenal cross-section may be measured by the diameter of a device it can accommodate.

Work in connection with the present invention has found that fallopian tubes can vary significantly in inner lumen cross-sectional sizes. The maximum diameter of a device which a fallopian tube can accommodate at its smallest point can range anywhere from 0.2 to 1.5 mm. For devices having a fixed cross-section, relatively large diameters will make the device more difficult to deliver. However, if the device is made too small, it can be more easily ejected from the fallopian tube. While fixed cross-sectional devices may still be effective (for example, by providing a range of different device sizes), the use of a radially expandable tubular structure such as free ended helical coil 204 allows the device to compensate for the substantially anatomical differences between users.

As generally described above, catheter 256 may optionally be positioned by first accessing the fallopian tube with a guidewire, and then advancing the catheter over the positioned guidewire. Alternatively, the catheter and contraceptive device may be advanced distally using the distal end of the primary coil as a guidewire. Regardless, once the contraceptive device is positioned at the desired axial location (generally from adjacent the isthmus to the intraluminal region, but optionally anywhere from the cornual area to adjacent the distal fimbria), catheter 256 is withdrawn proximally while restraining the contraceptive device axially with the proximal end of corewire 214. As catheter 256 is withdrawn, secondary coil 204 expands radially and engages the surrounding tubal wall W, as illustrated in Fig. 15C. Secondary coil 204 may optionally be torqued against the surrounding tubal wall from the proximal end of corewire 214, after which the corewire is unthreaded from the contraceptive device and removed.

Although the tissues of the tubal wall protrude between the windings of secondary coil 204, a significant portion of lumen L remains open. Nonetheless, functional occlusion is provided so long as the deployed device adequately interferes with fertilization so as to inhibit conception. Functional occlusion may be enhanced by the

formation of scar tissues and the growth of tissues from the tubal wall so as to occlude lumen L (ideally both inside and outside of the tubular retention structure), as illustrated in Fig. 15D. Such scar tissue formation will also aid in anchoring the device.

As can be understood with reference to Fig. 15D and Fig. 16, open areas within the contraceptive device along the axis of fallopian tube F can present some risk of providing a passageway for fertilization. To avoid providing a prosthetic lumen defined by the inner surface of primary coil 202 after corewire 214 is removed, a detachable delivery wire 260 is formed in two pieces. Distal delivery wire 264 is coupled to proximal delivery wire 262 by a threaded fastener 266. Fastener 266 provides column strength to the detachable delivery wire. This allows the distal portion of the delivery wire to remain within the primary coil when the contraceptive device is detached. Clearly, a wide variety of coupling mechanisms might be used. Advantageously, a threaded coupler allows the device to be torqued in one direction and detached by rotating the proximal delivery wire 262 in the other direction, generally as described above.

The use of primary coil 202 (in combination with corewire 214) as a guidewire can be understood with reference to Fig. 15E. The good proximal column strength of the corewire and the distally increasing flexibility of the combined corewire and primary coil at the distal end of the delivery device greatly facilitates axially advancing the device within fallopian tube F. The ability of the corewire 214 to transmit torque can also help advance the delivery system distally, as well as allowing the user to embed secondary coil 204 into the surrounding tubal wall. As can also be understood with reference to Fig. 15E, the use of a straight primary coil in a portion of the fallopian tube having significant axial curvature results in resilient engagement of the coil against the tubal wall, and can thereby provide anchoring similar to that described above for pre-bent coils in straight lumens.

Referring now to Fig. 17, a kit 300 includes contraceptive system 212 (in which straight contraceptive device 200 is mounted on corewire 214) within a sterile package 302. Also included in kit 300 are instructions 304, the sterile package and instructions being disposed in packaging 306. The instructions may set forth any of the method steps for using a contraceptive system as described hereinabove. Delivery system 212 may be protected by a protective sheath 308, and other system components described hereinabove may also be included. Also visible in Fig. 17 is the proximal torquable handle 310 of the delivery system.

Instructions 304 will often comprise printed material, and may be found in whole or in-part on packaging 306 or sterile packaging 302. Alternatively, instructions 304 may be in the form of a recording disk or other computer readable data, a video tape, a sound recording, or the like.

Alternative radially expandable retention structures are illustrated in Figs. 18A through C. A slotted tube retention structure 320 can shorten and expand within the fallopian tube. In general, such expansion may be the result of external forces (such as actuation of a two part delivery system 322), or the retention structure may self-expand when released *in situ*. Forcibly expanded retention structures may have a latching mechanism which prevents collapse when the device is detached from the delivery system in the fallopian tube, and such detachment may be effected by any of the mechanisms described hereinabove.

Still further alternative retention structures may be used in place of helical secondary coil 204 and slotted tube 320. For example, a Malecott retention structure 324 or a braided filament retention structure 326 might be expanded to engage a surrounding tubal wall. In some cases, tubal anchoring may be enhanced by including two or more retention structures, or by providing small barbs which extend axially and/or radially from the expanded retention structure to prevent axial migration. Preferably, such barbs would be too short to perforate through the tubal wall.

In conclusion, the present invention provides a contraceptive intrafallopian device which may be positioned without surgery. While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, a wide variety of secondary shapes, including open loops, continuous bends, sinusoidal curves, or the like, may be imposed on the primary coil. Additionally, aspects of these intrafallopian contraceptive devices which are described separately may often be combined (for example, a self-guiding device may also promote ingrowth to affix the device in the fallopian tube). Therefore, the above description should not be taken as limiting the scope of the invention, which is defined instead solely by the appended claims.

WHAT IS CLAIMED IS:

1. An intrafallopian contraceptive device comprising:

a proximal anchor having a proximal cross-section;

a distal anchor having a distal cross-section; and

a lumen-traversing region extending between the proximal anchor and the distal anchor, the lumen traversing region comprising a resilient structure and a ribbon wound over the outer surface of the resilient structure, the lumen traversing region having a helical outer surface and a helical cross-section which is smaller than both the proximal cross-section and the distal cross-section.

2. An intrafallopian contraceptive device as claimed in claim 1, wherein the ribbon includes a sharp outer edge.

3. An intrafallopian contraceptive device as claimed in claim 1 wherein at least one of the proximal anchor, the distal anchor, and the lumen-traversing region comprises copper.

4. An intrafallopian contraceptive device as claimed in claim 1 wherein at least one of the proximal anchor and the distal anchor comprises a resilient structure biased to form a secondary shape.

5. An intrafallopian contraceptive device comprising:

a proximal anchor having a proximal cross-section;

a distal anchor having a distal cross-section; and

a lumen-traversing region extending between the proximal anchor and the distal anchor, the lumen traversing region having a helical outer surface and a helical cross-section which is smaller than both the proximal cross-section and the distal cross-section;

wherein at least one of the proximal anchor and the distal anchor comprises a resilient structure biased to form a secondary shape, and wherein the resilient structure comprises a primary coil.

6. An intrafallopian contraceptive device as claimed in claim 5, wherein the primary coil comprises a material selected from the group consisting of beryllium, stainless steel, platinum, and shape memory alloy.

7. An intrafallopian contraceptive device as claimed in claim 6, wherein the primary coil comprises an alloy including beryllium and copper.

8. An intrafallopian device as claimed in claim 5, wherein the primary coil comprises an alloy including at least 75% copper.

9. An intrafallopian contraceptive device as claimed in claim 1, wherein a lumen extends from a proximal end of the proximal anchor to near a distal end of the distal anchor, and wherein the intrafallopian contraceptive device is restrainable in a straight configuration by a corewire within the lumen.

10. An intrafallopian contraceptive device comprising:

a primary coil having a distal loop, a proximal loop, and an intermediate straight section between the distal loop and the proximal loop; and

a helical ribbon wound over at least a portion of the intermediate section.

11. An intrafallopian contraceptive device as claimed in claim 10, wherein the ribbon has a width in the range between .005 and .1 inch.

12. An intrafallopian contraceptive device as claimed in claim 11, wherein the ribbon has a thickness in the range between .001 and .2 inch.

13. An intrafallopian contraceptive device as claimed in claim 10, wherein the ribbon has a pitch in the range between .01 and .2 inch.

14. An intrafallopian contraceptive device as claimed in claim 10, wherein the device has a length in the range between 1.5 cm and 7.5 cm when in a relaxed state.

15. An intrafallopian contraceptive device as claimed in claim 10, wherein the device comprises copper.

16. An intrafallopian contraceptive device as claimed in claim 15, wherein the primary coil comprises a material selected from the group consisting of beryllium, stainless steel, platinum, and shape memory alloy.

17. An intrafallopian contraceptive device as claimed in claim 16, wherein the primary coil comprises an alloy including beryllium and copper.

18. An intrafallopian contraceptive device as claimed in claim 10, wherein the primary coil includes a lumen which extends from a proximal end of the proximal loop to near the distal end of the distal loop.

19. An intrafallopian contraceptive device as claimed in claim 10, wherein the primary coil has an outer diameter in the range between .2 mm and 5 mm.

20. An intrafallopian contraceptive device as claimed in claim 10, wherein the distal loop and the proximal loop have outer diameters of at least 3 mm when in a relaxed state.

21. An intrafallopian contraceptive system comprising:

a primary coil having a distal loop, a proximal loop, an intermediate straight section between the distal loop and the proximal loop, and a lumen from a proximal end of the proximal loop to near a distal end of the distal loop;

a helical ribbon wound over at least a portion of the intermediate section; and

a corewire removably disposed within the lumen of the primary coil, the corewire restraining the primary coil in a straight configuration.

22. An intrafallopian contraceptive system as claimed in claim 21, wherein the primary coil comprises copper.

23. An intrafallopian contraceptive system as claimed in claim 21, wherein the corewire is threadably received by the primary coil.

24. An intrafallopian contraceptive system as claimed in claim 21, further comprising a release catheter slidably disposed over the corewire proximally of the primary coil, the release catheter having a distal primary coil engaging surface for restraining the primary coil while the corewire is withdrawn proximally.

25. An intrafallopian contraceptive method comprising:

restraining a pre-formed resilient structure in a straight configuration with a corewire extending into the resilient structure, the resilient structure including a lumen-traversing region having a helical outer surface;

transcervically introducing the restrained resilient structure into a target region of a fallopian tube; and

withdrawing the corewire from within the introduced resilient structure to mechanically anchor the resilient structure within the fallopian tube, at least a portion of the

resilient structure assuming a secondary shape which is larger in cross-section than the fallopian tube when the corewire is withdrawn.

26. A method as claimed in claim 25, wherein the target region is adjacent to an ostium of the fallopian tube.

27. A method as claimed in claim 26, wherein the target region extends distally of an isthmus of the fallopian tube.

28. A method as claimed in claim 25, further comprising torquing the corewire to anchor the resilient structure, the helical shape having a sharp outer edge.

29. A method as claimed in claim 25, wherein the withdrawing step comprises forming a distal anchor from a portion of the resilient structure which is distal of the lumen-traversing region, and forming a proximal anchor from a portion of the resilient structure which is proximal of the lumen-traversing region, the distal portion and the proximal portion assuming the secondary shape.

30. An intrafallopian contraceptive method comprising:

restraining a resilient structure in a straight configuration over a corewire, the resilient structure including a lumen-traversing region having a helical outer surface;

transcervically introducing the resilient structure into a target region of a fallopian tube; and

withdrawing the corewire from the resilient structure to mechanically anchor the resilient structure within the fallopian tube, at least a portion of the resilient structure assuming a secondary shape which is larger in cross-section than the fallopian tube,

wherein the withdrawing step comprises unthreading the corewire from the resilient structure.

31. A method as claimed in claim 25, wherein the withdrawing step comprises axially restraining the resilient structure with a release catheter while proximally withdrawing the corewire from within the resilient structure, the release catheter being slidably disposed over the corewire proximally of the resilient structure.

32. A method as claimed in claim 25, further comprising applying an electrical current from the corewire and through the resilient structure to the fallopian tube to desiccate a tubal wall and anchor the resilient structure within the fallopian tube prior to withdrawing the corewire, so as to permanently prevent conception.

33. An intrafallopian sterilization method comprising:

transcervically introducing a structure into a target region of a fallopian tube, the structure being releasably attached to a distal end of an elongate body;

applying an electrical current through the elongate body to the structure, and through the structure to the fallopian tube to permanently anchor the structure within the fallopian tube; and

releasing the structure from the elongate body and withdrawing the elongate body.

34. An intrafallopian contraceptive device comprising:

a proximal anchor;

a pre-formed distal anchor which is adapted for insertion into a fallopian tube, and which is capable of imposing resilient anchoring forces against an inner surface of a tubal wall; and

a lumen-traversing region extending between the proximal anchor and the distal anchor, the lumen traversing region comprising means for affixing the intrafallopian contraceptive device to the adjacent tubal wall while the

device is restrained within the fallopian tube by the proximal and distal anchors.

35. An intrafallopian contraceptive device as claimed in claim 34, wherein the affixing means comprises a helical outer surface which can be embedded into the adjacent tubal wall without perforating the tubal wall.

36. An intrafallopian contraceptive device as claimed in claim 34, wherein the affixing means comprises means for promoting tissue growth of the tubal wall so as to permanently affix the intrafallopian contraceptive device within the fallopian tube.

37. An intrafallopian contraceptive device as claimed in claim 36, wherein the growth promoting means comprises an element selected from the group containing polyester fibers for promoting tissue ingrowth and an electrically conductive surface coupleable to the tubal wall so as to promote formation of scar tissues.

38. An intrafallopian contraceptive device comprising:

a pre-formed proximal anchor having a resilient coil which is restrainable in a straight configuration for insertion into a fallopian tube, and which is capable of imposing resilient anchoring forces against an inner surface of a tubal wall;

a pre-formed distal anchor having a resilient coil which is restrainable in a straight configuration for insertion into the fallopian tube, and which is capable of imposing resilient anchoring forces against the inner surface of the tubal wall; and

a lumen-traversing region extending between the proximal and distal anchors, the lumen-traversing region comprising a resilient structure having a helical outer surface which is adapted to engage the inner surface of the tubal wall so as to prevent expulsion of the intrafallopian

contraceptive device while the proximal and distal anchors impose the anchoring forces.

39. An intrafallopian contraceptive method comprising:

transcervically introducing a pre-formed resilient structure into a target region of a fallopian tube;

imposing an anchoring force against a tubal wall of the fallopian tube by resiliently engaging an inner surface of the tubal wall with the resilient structure; and

affixing the resilient structure within the fallopian tube with a lumen-traversing region of the resilient structure.

40. A method as claimed in claim 39, wherein the affixing step comprises promoting tissue ingrowth of the tubal wall surrounding the resilient structure.

41. A method as claimed in claim 40, wherein the tissue ingrowth occludes the fallopian tube to inhibit conception.

42. A method as claimed in claim 39, further comprising promoting the formation of scar tissue by electrically energizing the resilient structure within the fallopian tube.

43. A tissue reaction contraceptive device for use in a fallopian tube, the fallopian tube having tubal tissues, the contraceptive device comprising:

a coil having a proximal end and a distal end and defining an axis therebetween, the coil being axially flexible and having a cross-section suitable for insertion into the fallopian tube; and

an element disposed along the coil, the element adapted to incite a tissue reaction in the tubal tissues adjacent the coil so as to inhibit conception.

44. A contraceptive device as claimed in claim 43, wherein the element comprises a braided or woven polyester.

45. A contraceptive device as claimed in claim 43, wherein the element comprises a perforate material defining surface pores which promote tissue ingrowth of the tubal tissues.

46. A contraceptive device as claimed in claim 45, wherein the perforate material comprises a member selected from the group consisting of PTFE, ceramic, or microporous polymer.

47. A contraceptive device as claimed in claim 43, wherein the element comprises a polymer coating which promotes at least one of scarring of the tubal tissues, ingrowth of the tubal tissues, and sclerosing of the tubal tissues.

48. A tissue ingrowth contraceptive device for use in a fallopian tube having a tubal tissue, the contraceptive device comprising:

a tubular retention structure having a proximal end, a distal end, and an axis therebetween, the retention structure being axially flexible and insertable within the fallopian tube;

a material which can incite ingrowth of the tubal tissue therein, the ingrowth material attached to the retention structure.

49. A contraceptive device as claimed in claim 48, wherein the material comprises braided or woven polyester.

50. A contraceptive device as claimed in claim 49, wherein the retention structure comprises a perforate frame having at least one radial opening, and wherein the braided or woven polyester extends radially beyond the tubular retention structure through the at least one radial opening.

51. A contraceptive device as claimed in claim 48, wherein the retention structure comprises a helical outer coil having a sharp edge.

52. A contraceptive device as claimed in claim 48, further comprising an inner coil disposed within the tubular retention structure, wherein at least a portion of the material is disposed in an annular space between the inner coil and the retention structure.

53. A contraceptive device as claimed in claim 50, wherein the inner coil extends distally beyond the retention structure with sufficient resilient flexibility to help guide the contraceptive device axially within the fallopian tube.

54. A tissue ingrowth contraceptive device for use in a fallopian tube, the contraceptive device comprising:

a resilient elongate body having a proximal end and a distal end and defining an axis therebetween;

a retention structure disposed along the resilient body, the retention structure adapted to restrain the resilient body within the fallopian tube;

a bond affixing the retention structure to the resilient body;

wherein at least one of the resilient body, the retention structure, and the bond comprises a microporous material which promotes tissue ingrowth therein.

55. A contraceptive method comprising:

transcervically inserting a contraceptive device within a fallopian tube by resiliently deflecting a distal body of the contraceptive device against a tubal wall so that the distal body guides the contraceptive device axially along the fallopian tube; and

inciting a tissue reaction of tubal tissues with an element of the contraceptive device so as to affix the contraceptive device within the fallopian tube.

56. A contraceptive method as claimed in claim 55, wherein the inciting a tissue reaction step comprises promoting tissue ingrowth into the element.

57. A contraceptive method as claimed in claim 56, wherein the inciting a tissue reaction step comprises mechanically promoting scar formation by embedding a radially oriented edge into the tubal wall without penetrating through the tubal wall.

58. A contraceptive method as claimed in claim 55, wherein a polymeric coating of the contraceptive device incites a tissue reaction selected from the group consisting of scarring, ingrowth, or sclerosing.

59. A contraceptive device for use in a fallopian tube having a tubal wall, the contraceptive device comprising:

a tubular retention structure having a proximal end, a distal end, and an axis therebetween, the retention structure radially expandable *in situ* from a narrow diameter configuration, the retention structure in the narrow configuration having a first diameter suitable for axial insertion into the fallopian tube, the expanded retention structure having a second diameter larger than the first diameter and adapted to engage the surrounding tubal wall and retain the contraceptive device within the fallopian tube.

60. A contraceptive device as claimed in claim 59, wherein the retention structure comprises a resilient helical coil.

61. A contraceptive device as claimed in claim 60, wherein the coil expands resiliently to safely engage the tubal wall throughout a range of tubal cross-sectional sizes.

62. A contraceptive device as claimed in claim 61, wherein the coil resiliently expands to open diameters throughout the range from about 0.10 to about 1.0 mm with an

expansion force sufficient to help retain the contraceptive device in the fallopian tube and insufficient to penetrate through the tubal wall.

63. A contraceptive device as claimed in claim 60, wherein the coil has a sharp outer edge.

64. A contraceptive device as claimed in claim 60, further comprising a conception inhibiting body attached to the coil.

65. A contraceptive device as claimed in claim 64, wherein a portion of the coil is affixed to the body and an end of the coil moves relative to the body when the coil expands from the first diameter.

66. A contraceptive device as claimed in claim 64, wherein the body extends distally of the coil and is resiliently flexible to help guide the contraceptive device distally within the fallopian tube.

67. A contraceptive device as claimed in claim 66, further comprising woven or braided polyester attached to the body.

68. A contraceptive device for use in a fallopian tube having a tubal wall, the contraceptive device comprising:

a conception inhibiting body defining an axis;

a helical coil disposed about the body, a portion of the helical coil movable relative to the body so that the helical coil can expand resiliently throughout a range of tubal cross-sectional sizes to radially engage the surrounding tubal wall and safely affix the contraceptive device within the fallopian tube.

69. A contraceptive method comprising:

introducing a contraceptive device into a fallopian tube;

radially expanding a retention structure of the contraceptive device within the fallopian tube so that the retention structure engages a tubal wall and affixes the contraceptive device within the fallopian tube.

70. An intrafallopian contraceptive device for use in a fallopian tube, the contraceptive device comprising:

an elongate coil having a proximal end, a distal end, and an axis therebetween, the axis being substantially straight when the coil is at rest, the coil being axially resilient to facilitate insertion of the body axially into the fallopian tube, the device being adapted to be retained within the tube so as to inhibit conception.

71. A contraceptive device as claimed in claim 70, further comprising an element disposed along the coil, the element adapted to affix the body within the fallopian tube.

72. An intrafallopian contraceptive device for use in a fallopian tube, the tube having a tubal wall with a tubal cross-section and an axial curvature, the contraceptive device comprising:

an elongate body having a proximal end and a distal end and defining an axis therebetween, the body having a cross-section suitable for axial insertion within the tubal cross-section, at least a portion of the body being straighter than the axial curvature of the fallopian tube, the body being sufficiently flexible to deflect against the tubal wall without injuring the tubal wall, the body being sufficiently resilient to impose an anchoring force against the tubal wall when the straight portion flexes along the axial curvature of the fallopian tube.

73. A contraceptive device as claimed in claim 72, further comprising an element disposed along the body, the element adapted to affix the body within the fallopian tube.

74. A contraceptive device as claimed in claim 73, wherein the body is adapted to resiliently engage the tubal wall with sufficient force to retain the body in the fallopian tube during ingrowth of tubal wall tissues into the element.

75. A contraceptive device as claimed in claim 73, wherein the element is adapted to penetrate into the tubal wall without perforating through the tubal wall to mechanically retain the body in the fallopian tube.

76. A contraceptive device as claimed in claim 75, wherein the element is adapted to promote scar tissue.

77. A contraceptive device as claimed in claim 72, wherein the element comprises an electrode attached to the body, the electrode being oriented to engage and desiccate the tubal wall.

78. A contraceptive device for use in a fallopian tube having an axis, the contraceptive device comprising:

a structure having a proximal end, a distal end, and an axis therebetween, the structure adapted to provide effective tubal occlusion when disposed substantially coaxially within the fallopian tube;

an elongate member affixed to the occlusion structure, the member extending distally of the occlusion structure and being sufficiently flexible and axially resilient to help guide distal advancement of the occlusion structure within the fallopian tube.

79. A contraceptive device as claimed in claim 78, wherein the elongate member comprises a coil and a corewire.

80. A contraceptive device as claimed in claim 79, wherein the corewire is removable from the coil when the coil is disposed in the fallopian tube.

81. A contraceptive method comprising:

transcervically inserting an elongate resilient body into an axially curving fallopian tube so that the fallopian tube imposes an axial bend on the body, and so that the bent body imposes an anchoring force which helps anchor the bent body within the fallopian tube; and

affixing the anchored body within the fallopian tube so that the affixed resilient body inhibits conception.

82. A contraceptive method comprising:

transcervically inserting an intrafallopian contraceptive device along the fallopian tube by guiding the contraceptive device with a distal guidewire-like structure of the contraceptive device; and

retaining the device, including at least a portion of the guidewire-like structure, within the fallopian tube so that the device inhibits conception.

83. A contraceptive method as claimed in claim 82, further comprising removing a corewire of the guidewire-like structure from within a coil of the guidewire-like device while the device is retained within the fallopian tube and promoting ingrowth of tubal tissues into the contraceptive device.

84. A contraceptive kit comprising:

an intrafallopian contraceptive device; and

instructions describing methods steps including;

transcervically introducing the contractive device into a fallopian tube; and

affixing the contraceptive device within the tube.

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS

ABSTRACT OF THE DISCLOSURE

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device is enhanced by forming the structure at least in part from copper or a copper alloy. The device is anchored within the fallopian tube by a lumen-traversing region of the resilient structure which has a helical outer surface, together with a portion of the resilient structure which is biased to form a bent secondary shape, the secondary shape having a larger cross-section than the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. Optionally, permanent sterilization is effected by passing a current through the resilient structure to the tubal walls.

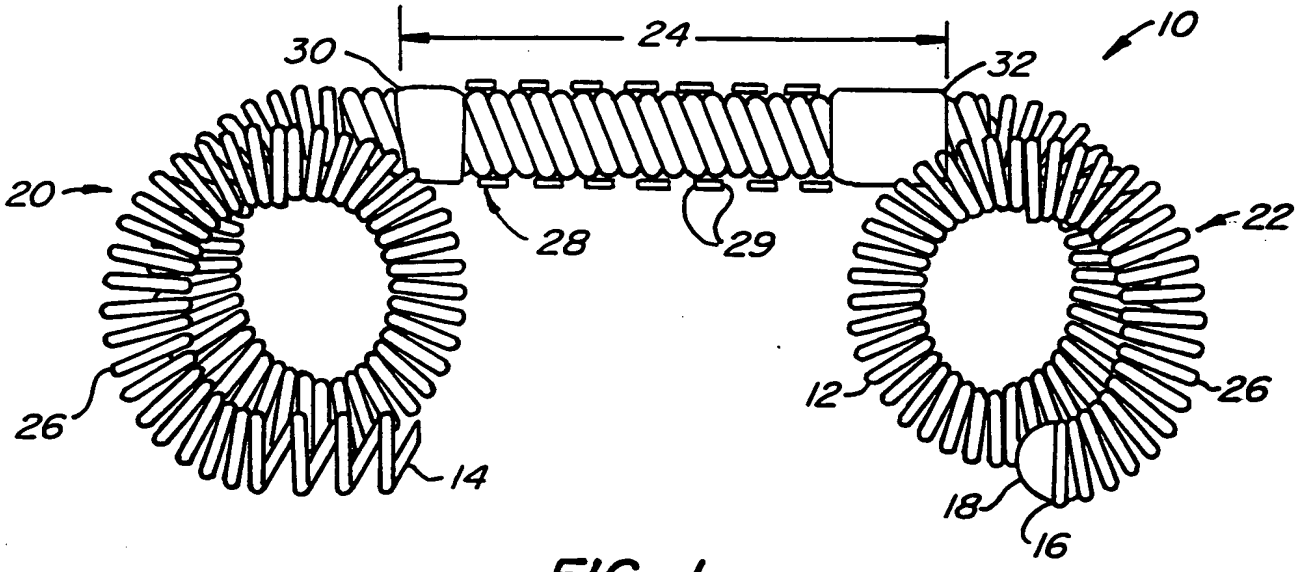

FIG. 1.

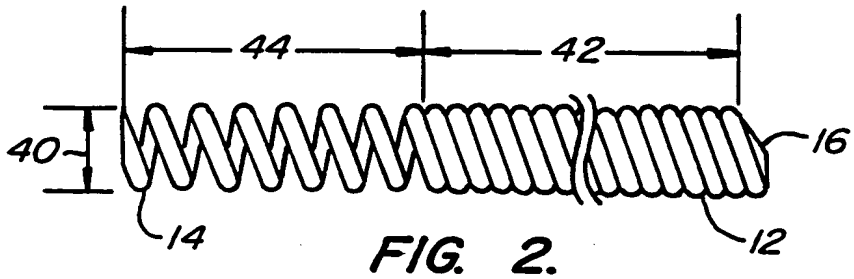

FIG. 2.

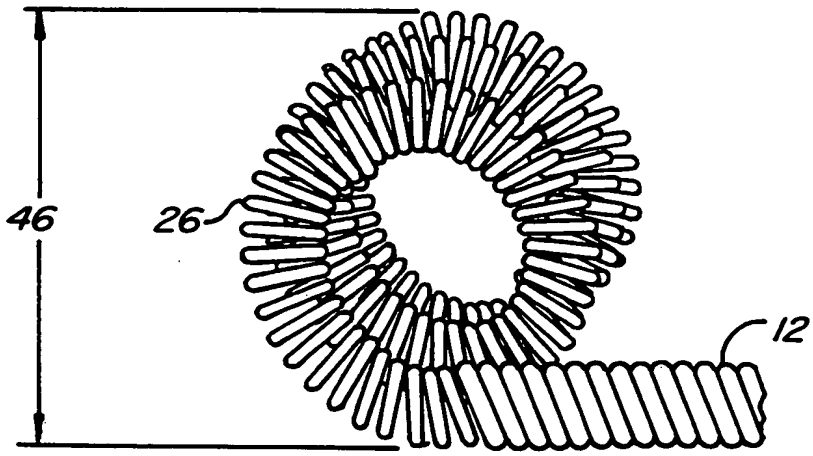

FIG. 3.

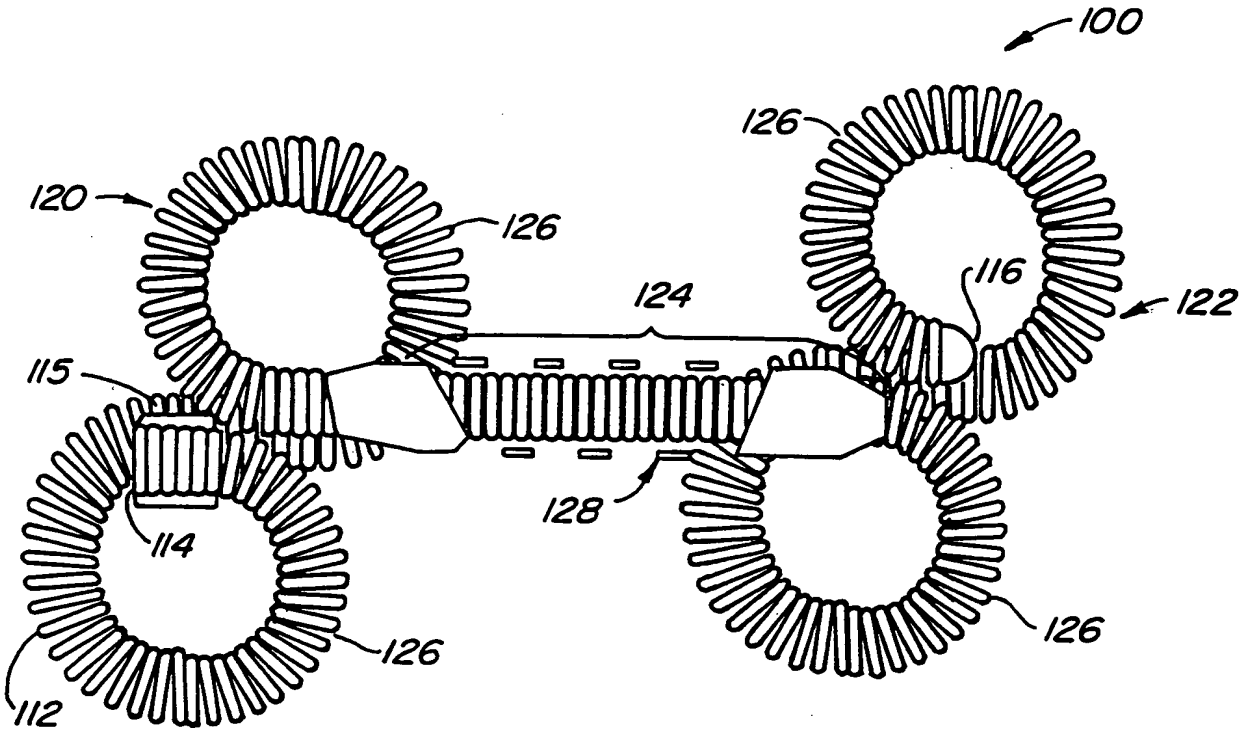

FIG. 6.

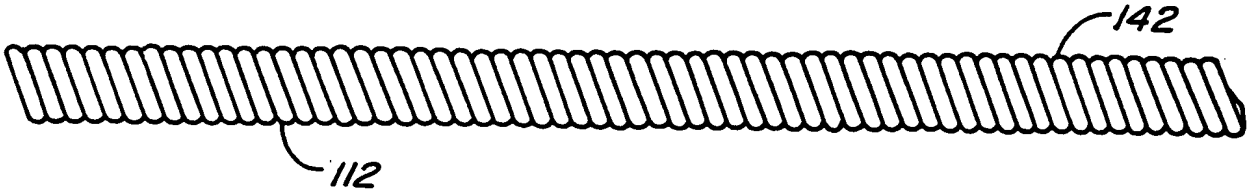

FIG. 7.

FIG. 4.

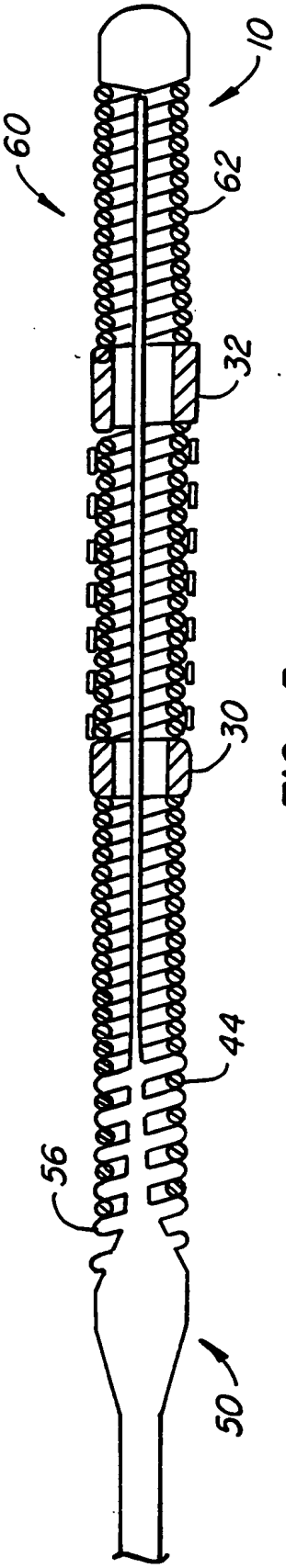

FIG. 5.

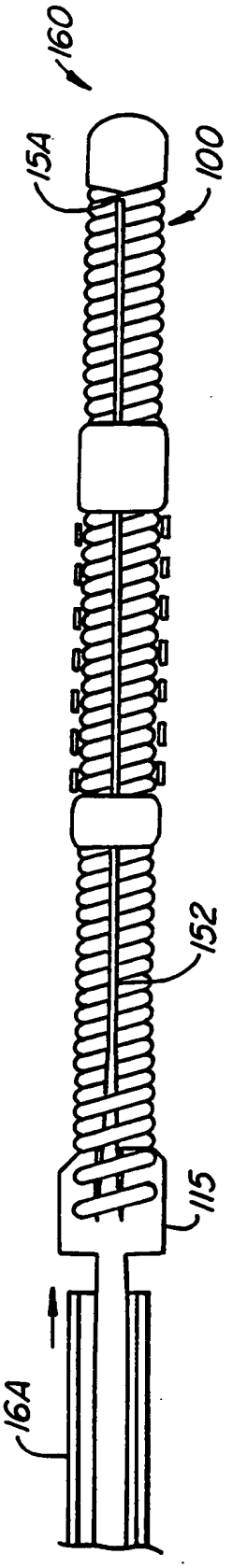

FIG. 8.

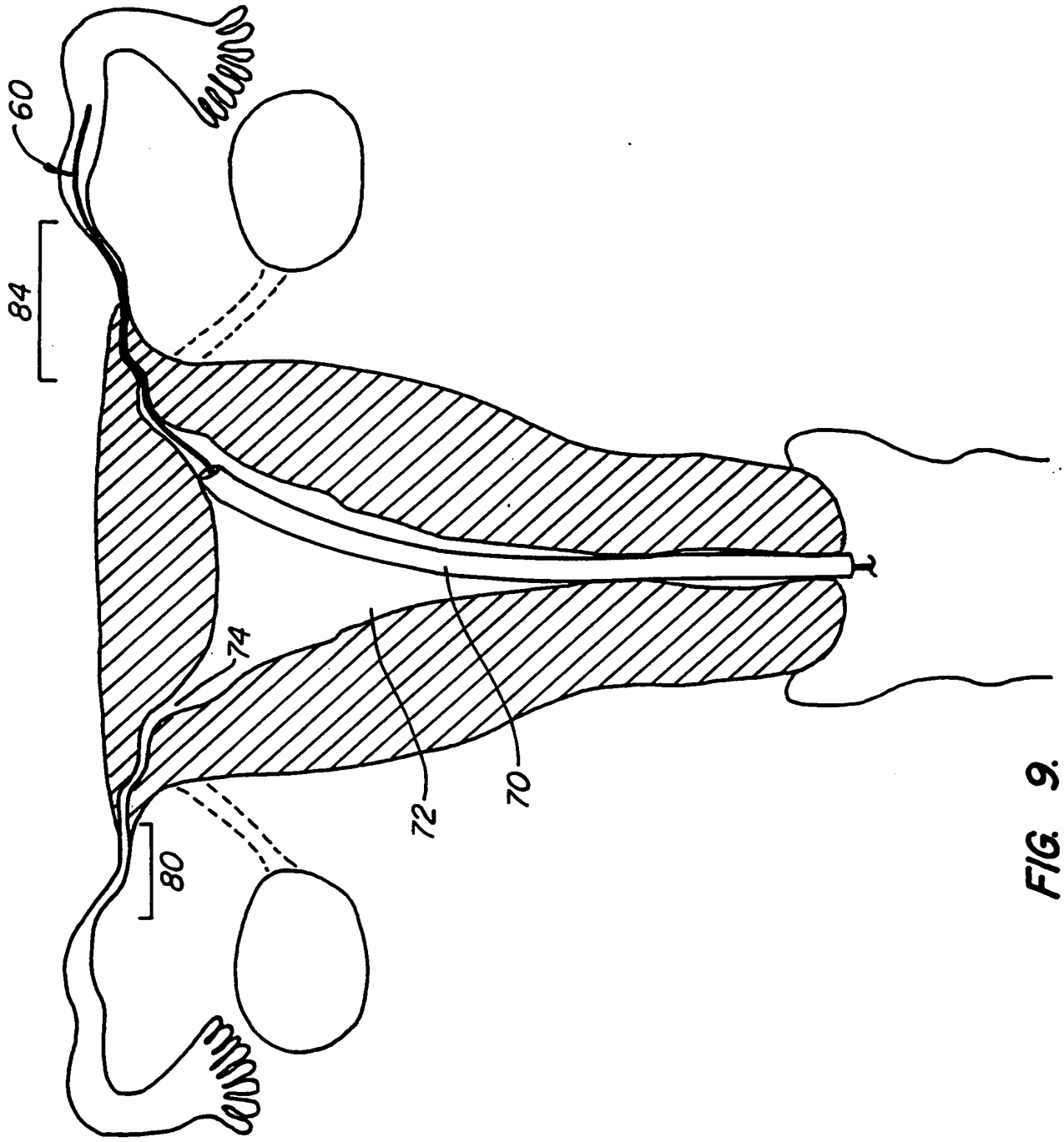

FIG. 9.

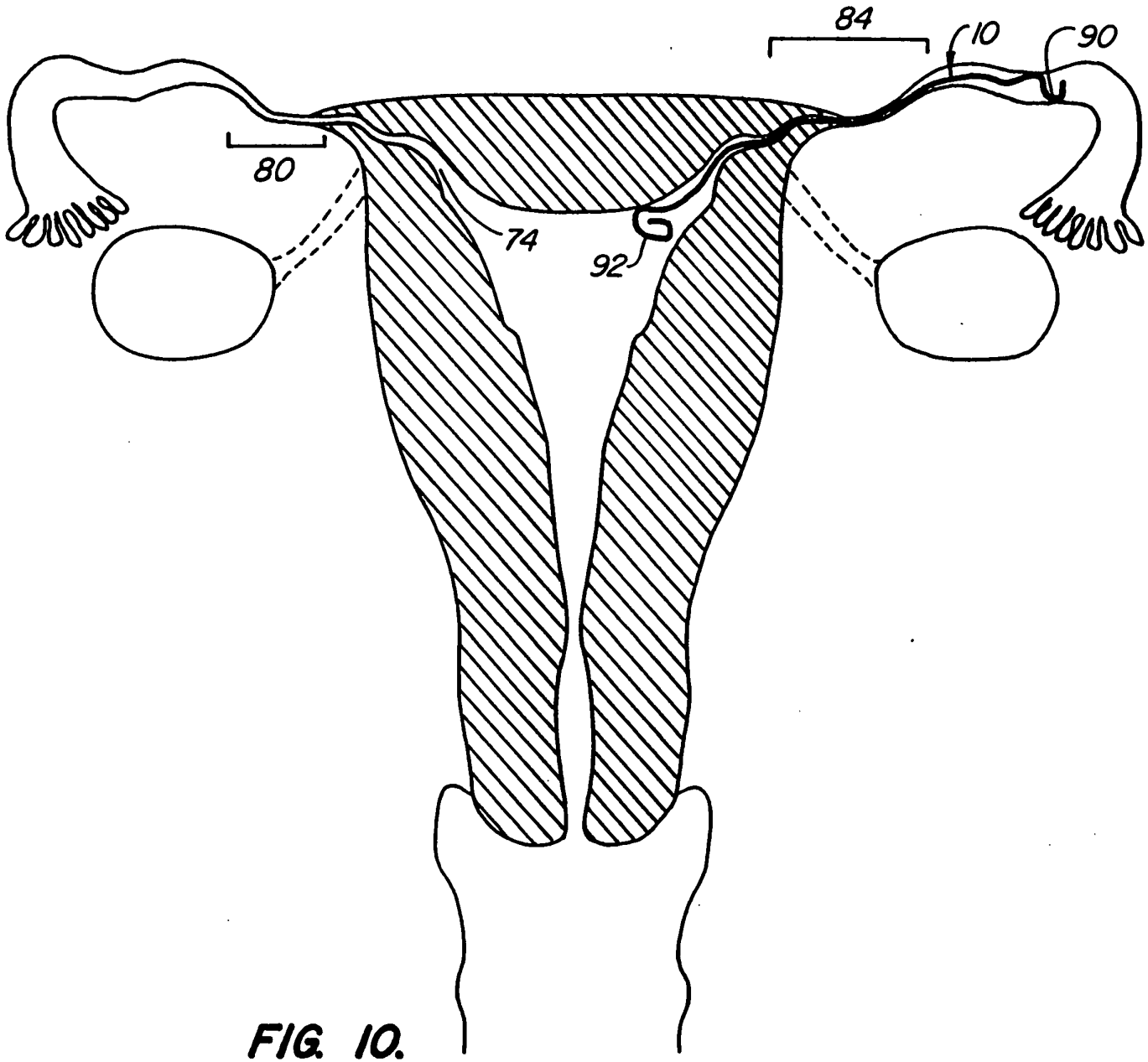

FIG. 10.

6355-25-2

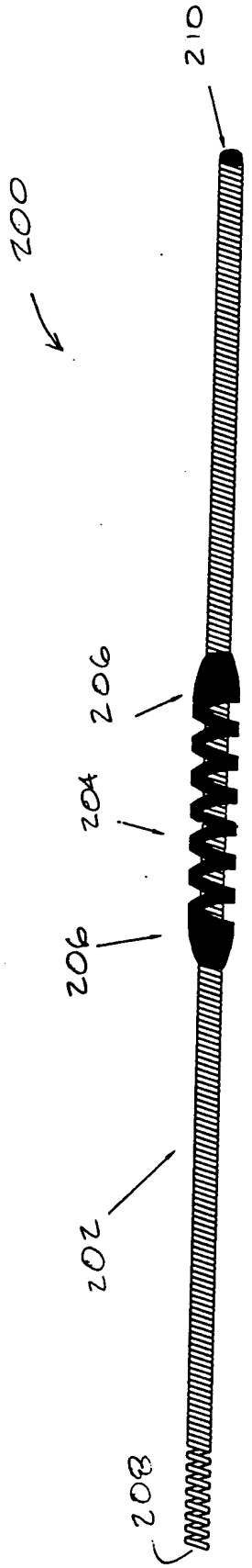

FIG-11A

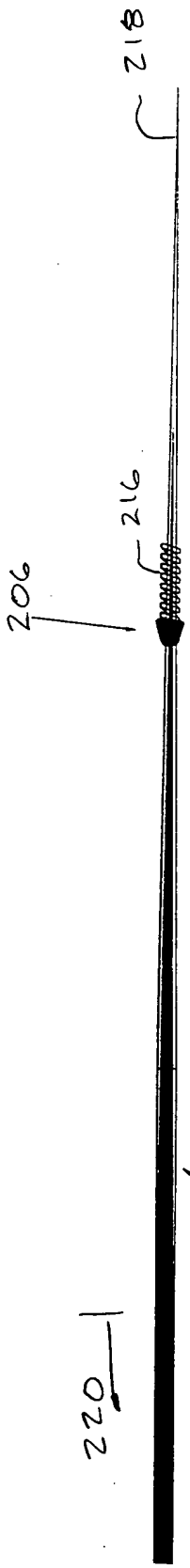

FIG-11B

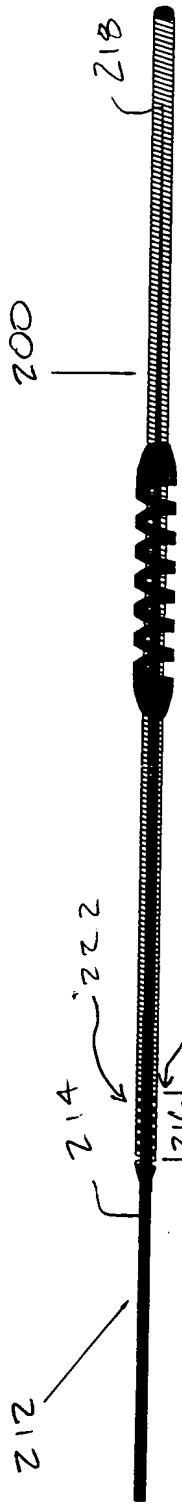

FIG-11C

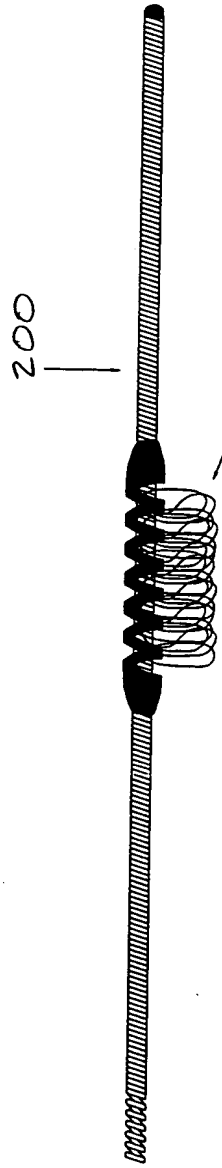

FIG-11D

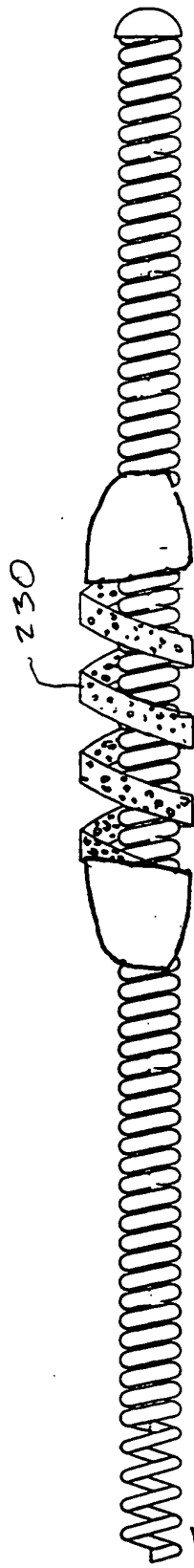

FIG-12A

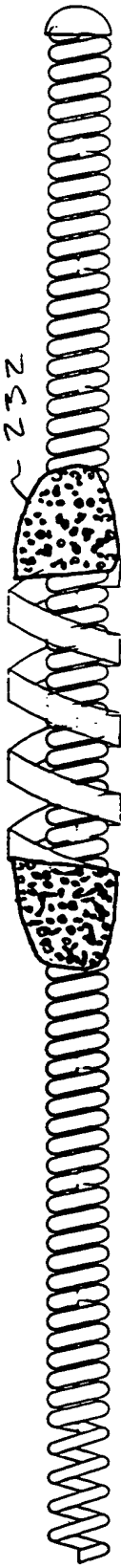

FIG-12B

FIG-12C

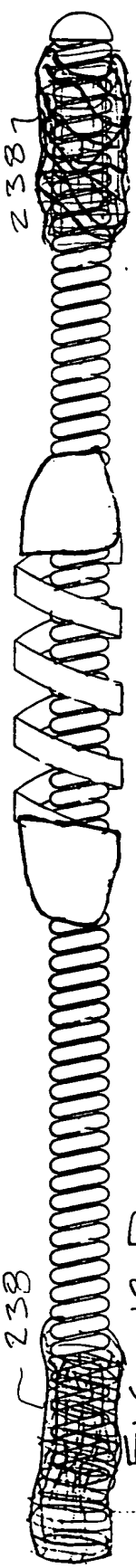

FIG-12D

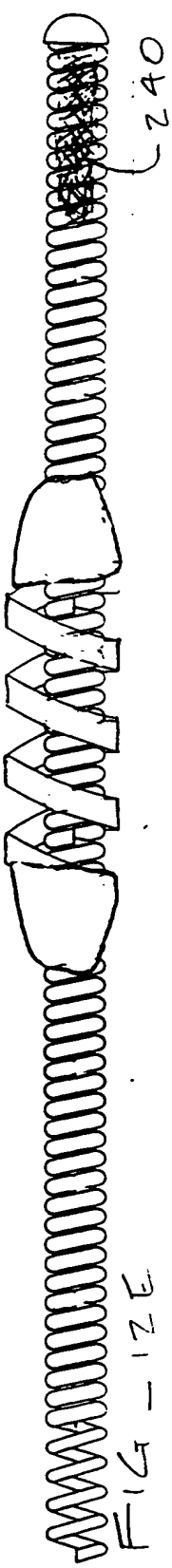

FIG-12E

FIG-13

FIG-14

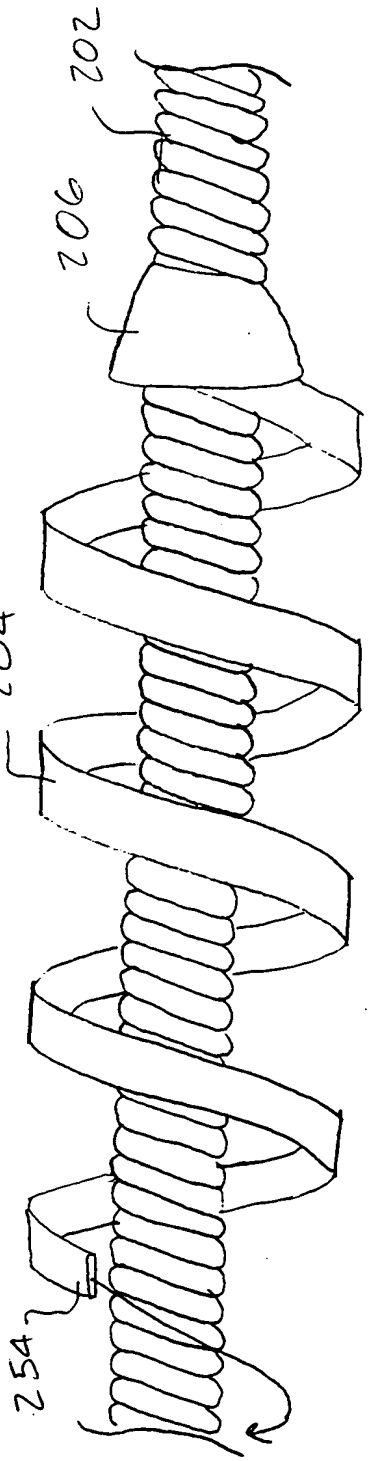

FIG-14A

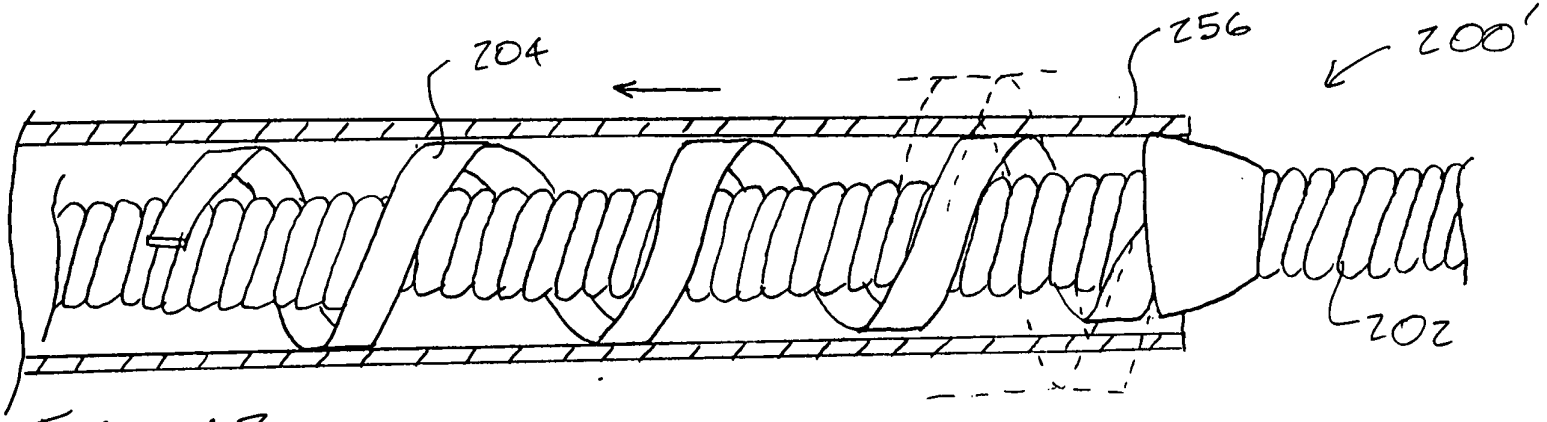

FIG_14B

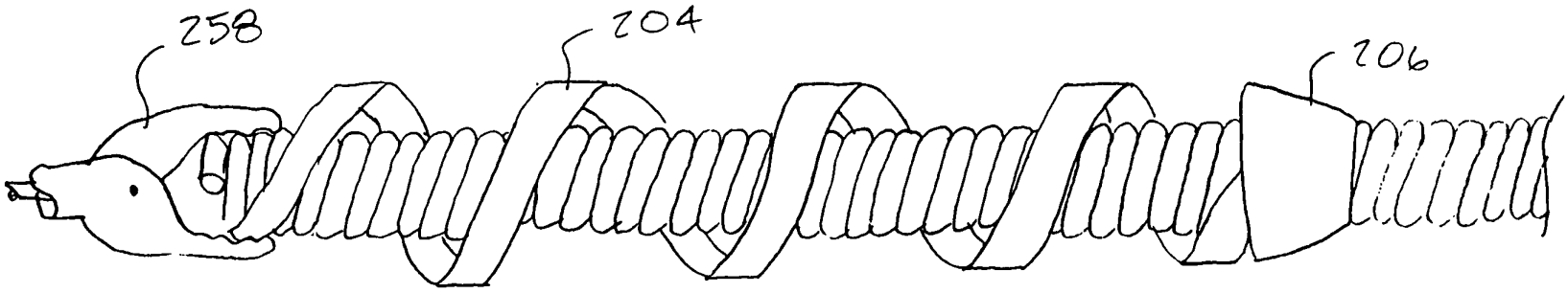

FIG_14C

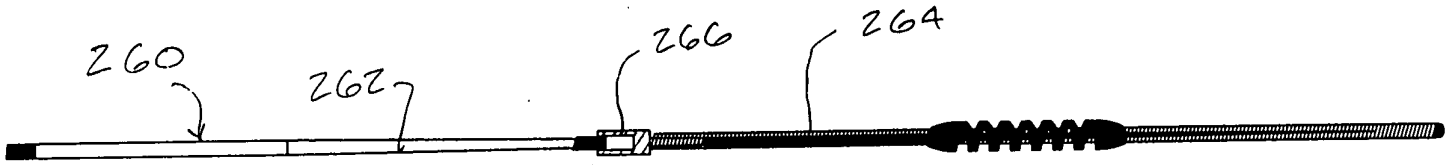

FIG_16

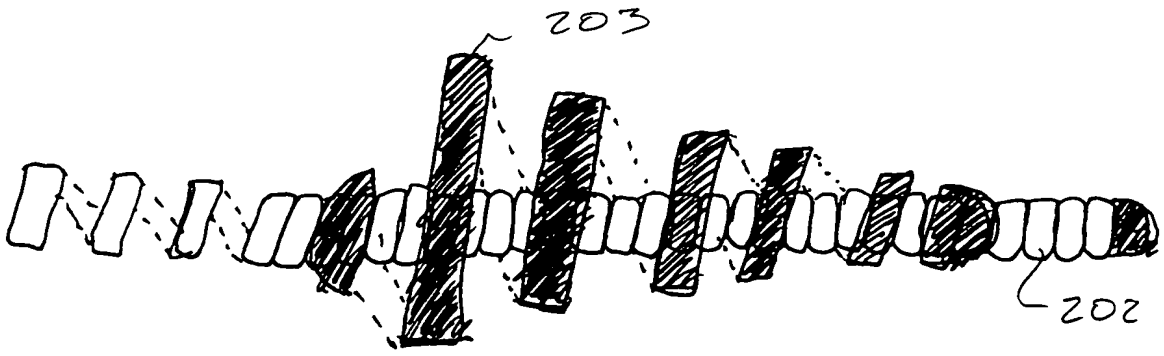

FIG. 14D

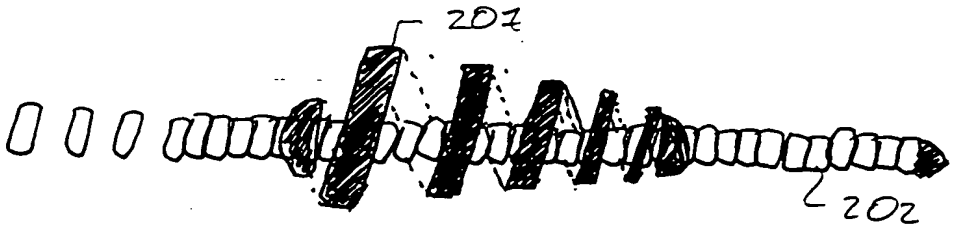

FIG. 14E

FIG. 18A

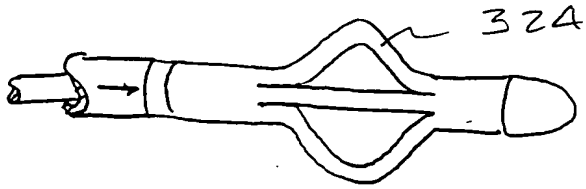

FIG. 18B

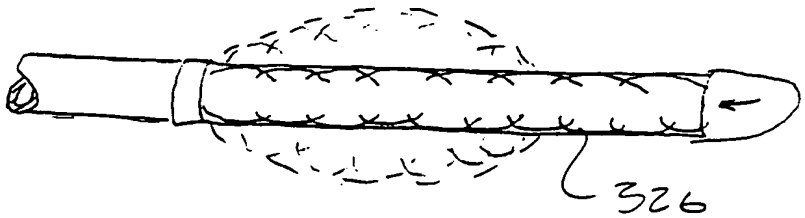

FIG. 18C

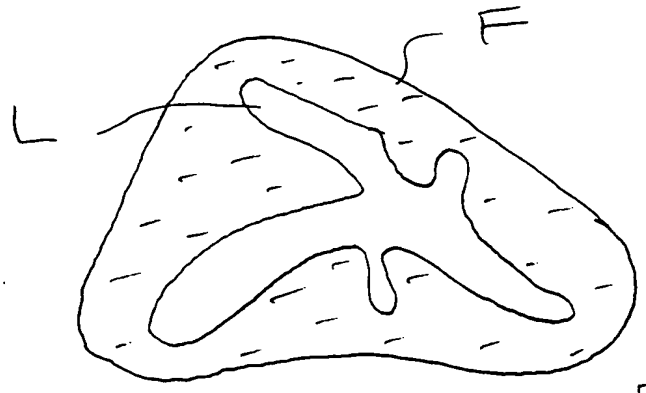

FIG_15A

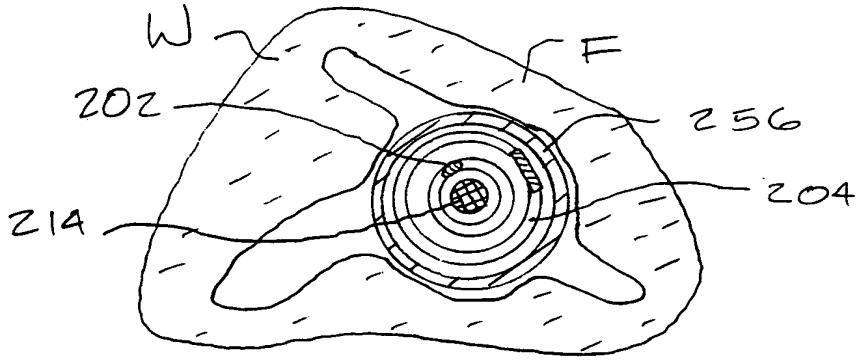

FIG_15B

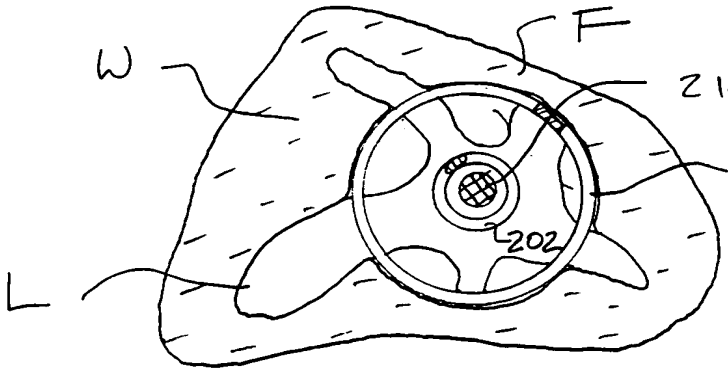

FIG_15C

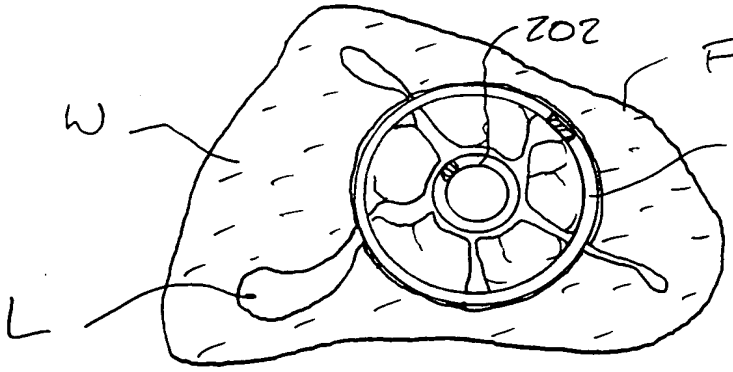

FIG_15D

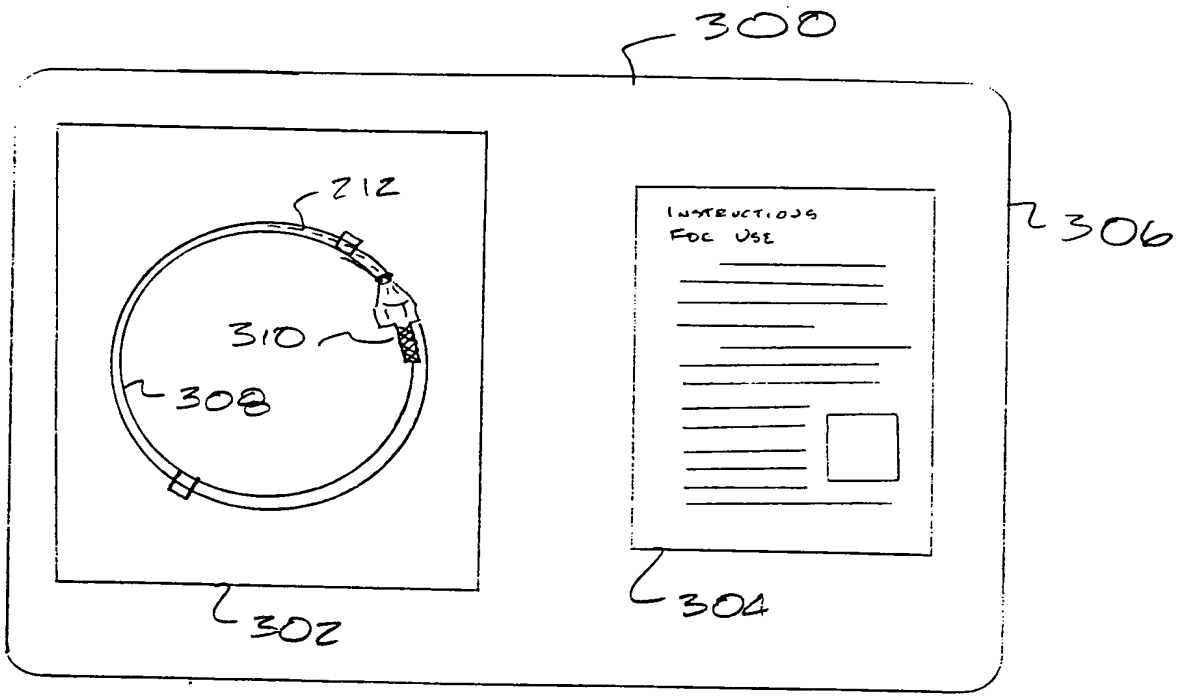

FIG_17

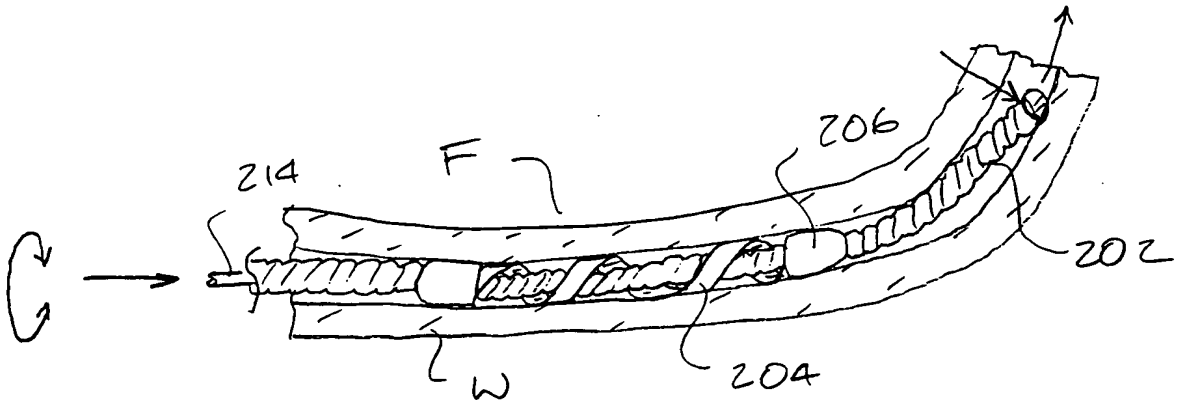

FIG_15E